CREATING A STANDARDIZED METHOD FOR IMPLEMENTING AI STUDIES IN DUTCH HEALTHCARE SYSTEMS.

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TITLE:	Creating a standardized method for implementing AI studies in Dutch healthcare systems.
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Abstract

Documentation is a vital part of healthcare, however, it can take up to 40% of a workweek for healthcare providers to do it. This valuable time can better be spent on providing care to patients. To decrease this, different AI system initiatives are introduced. One of these AI system initiatives is the Care2Report initiative, currently running a pilot at the UMCU. Unfortunately, the process and requirements of introducing these AI systems in the healthcare environment are not always clear. That is why this study explores the different processes and deliverables used for the implementation of AI systems within healthcare. There is aimed to document the different deliverables and activities at the hand of the meta-modelling technique by creating process delivery diagrams. For each of the different phases within the implementation process, process delivery diagrams have been created. Besides that, a deliverable list is supplied with background information about the different deliverables. Besides that, an ethical toolmap has been developed to give guidance in the implementation process and allow for the ethical implementation of AI systems within healthcare. At the hand of different interviews with domain experts, the models have been updated and the extended ethical toolmap has been cross-referenced with the different deliverables and activities.

Acknowledgements

Hereby I would like to thank my supervisor, Prof. Dr. Sjaak Brinkkemper, for the supervision of my thesis and the weekly feedback meeting. Also, I would like to thank my second supervisor, Dr. Sergio España Cubillo for taking the time to review this study. I would like to thank the people at Digital Health and the POS of the UMCU for their time and input for both the study and the pilot. I would like to thank the students of the C2R initiative for the feedback and the great time during the pilot done at the UMCU and the students of the study group for their weekly feedback, Last but not least, I would like to thank my girlfriend, family and friends for their uncanny support during the study.

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Abbreviations

AI	Artificial Intelligence
AVG	Algemene Verordening Gegevensbescherming
CCMO	Centrale Commissie Mensgebonden Onderzoek
CSV	Comma Seperated Values
DPIA	Data Protection Impact Assesment
EMR	Electronical Medical Record
GDPR	General Data Protection Regulation
HTA	Health Tech Assesment
IMDD	Investigational Medical Device Dossier
ISDM	Information System Development Methodology
ISO	International Standardization Organization
ME	Method Engineering
METC	Medical Ethical Testing Commission
ML	Machine Learning
MRQ	Main Research Question
PDD	Process Delivery Diagram
PIA	Privacy Impact Assessment
POS	Pre-Operative Screening
RQ	Sub-Research Question
SLR	Systematic Literature Review

SME	Situational Method Engineering
UI	User Interface
UMC	University Medical Centre
UMCU	University Medical Centre Utrecht
UX	User Experience

Chapter 1

Introduction

In 2019, the outbreak of the COVID-19 pandemic made a great impact on the world [88][127][137]. Not only was this a global event the world had not seen in years, causing unrest among citizens and economic loss, but it also displayed the many vulnerabilities in healthcare systems all over the world. This flawed situation was previously often already known by healthcare workers but did not seems apparent enough for governments to act upon. During the COVID-19 pandemic, the pressure on healthcare workers rose [149]. These increased levels of work pressure and stress on healthcare workers can have long-term consequences, such as mental health issues, leading to a higher absenteeism rate among healthcare workers [59].

These problems allow for new improvements and innovations among the different healthcare systems. Due to the lack of personnel, nurses and doctors work in a high-stress environment in which they often lack time to do other tasks than treating patients, such as administrative tasks [69][152] Spending large amounts of time on the documentation of patient treatment allows healthcare providers to spend less time on the patients themselves. It would seem to leave out these administrative tasks to be better for the quality of healthcare, however, the opposite is true.

The administration is a very important aspect of the healthcare system. Documentation of treatment and patient data improves healthcare as it allows for non-verbal communication between healthcare providers over time. Besides that, having documentation of patient history, symptoms, and other deficiencies is extremely important when treating a patient. Substantial information can already be deducted from previous encounters with a patient, improving patient treatment. Nowadays, the documentation of patient data is made easier by the use of the electronic medical record (EMR). Although it is made easier, documentation in healthcare is still far from perfect[38].

1.1 Research Objective

Doctors and nurses lack the time and resources to provide the quality of healthcare they aim to provide. One of the issues that arise is the number of administrative tasks doctors and nurses have to do. Although the quality of healthcare can greatly benefit from these administrative systems, such as the EMR, the number of systems and automatization is still in its infancy. However, the use of AI systems in artificial intelligence (AI) is growing with the current advancements in technology [121]. The quality of documentation is very important to prevent miscommunications, which in complex scenarios, such as patient treatment, can lead to extremely dangerous situations for the patient's health. To aid healthcare providers in decreasing the time spent on documentation, a pilot has started at the University Medical Centre Utrecht by implementing an AI system at one of the healthcare clinics. However, there is a lack of knowledge about how to properly introduce such an AI system in the different hospitals in the Netherlands by the implementation teams taking initiative.

1.1.1 Care2Report

This study is done as part of a project within Care2Report (C2R) [31]. This project concentrates on reducing time spent on documentation during the intake of the pre-operative screening clinic at the University Medical Center (UMC) in Utrecht. This page aims to give the reader context in which the overall study has taken place and give the reader a better understanding of the C2R initiative.

What is Care2Report

Care2Report aims to develop a generic software and hardware approach to help different healthcare institutes by reducing time spent on administrative tasks. This is done by designing and implementing different software and hardware innovations, using different non-intrusive methods. These innovations are designed at the hand of different design principles [85], to automatically document patient data into the electronic medical records and make working in healthcare take less effort.

Contribution

The C2R pilot group aims to support healthcare workers with doing their documentation by reducing the time spent reporting. This will be done at the hand of a non-intrusive audio system that processes audio into useful data which can be used in the EMR. Using speech-to-text can improve the quality of

provided healthcare [33]. Currently, active research is taking place to improve this process [81] [155].

This study explores the implementation of AI studies in Dutch healthcare. By exploring pitfalls from previous studies, mandatory steps which have to be taken when doing research in healthcare and the medical field, and deliverables during the implementation phase. Laying a basis to standardize these different steps can improve the success rate of different AI systems which aim to improve the healthcare system [143].

1.1.2 Objective

As is elaborated in the problem statement, there is a very high workload among Dutch healthcare workers. Healthcare institutes are aware of the current situation and promote ideas to be implemented. To help these initiatives, the threshold to enter a new study in the Dutch healthcare environment should be as little as possible. However, initiatives from outside the healthcare sector often have little knowledge about the processes currently present. This may lead to projects stopping while they could have been viable for the healthcare sector during the setup process while these might have been viable.

> *The objective of this study is to simplify the implementation of a new AI system within the Dutch healthcare environment.*

Doing this allows current and future AI studies in the field of Dutch healthcare to be better prepared for implementing their ideas and in such a way, plausibly aid the efficiency of Dutch healthcare. To reach this goal, there is aimed to map the different activities which have to be taken and the different deliverables which have to be introduced.

1.2 Research questions

To facilitate new studies and innovations within the healthcare system, this study aims to design a standardized method for digital products used in the administrative process of the Dutch healthcare system. This is done as part of a focus group in the C2R initiative which, at the hand of a pilot for automatizing administration for the pre-operative screening phase of the University Medical Centre Utrecht, is aimed to answer the following main research question:

MRQ: *What are the components of a method for implementing AI solutions in healthcare?*

To aid in answering the MRQ, it is split into four different sub-research questions (RQ), with each aiming to answer a different aspect of the MRQ.

RQ1: *How have previous AI studies and pilots been implemented in healthcare?*

The goal of **RQ1** is to provide an overview of how similar studies in the past have been conducted. As healthcare is already a place where a large number of studies are conducted, it should provide a stable basis for this study. This research question is answered at the hand of a literature study using a literature framework. This research question aims to identify the main difficulties of implementing an AI system in healthcare and to have testing criteria for the final model created as part of RQ4.

RQ2: *What are the requirements to initiate research within a healthcare clinic at the UMCU?*

The goal of **RQ2** is to provide a detailed description of the systems for researchers currently in place at the UMCU. This research question will also provide an overview of other aspects of doing research in healthcare such as ethics and which instances need to be contacted for certain studies. This study will use the literature study from RQ1 as a basis and build upon this with a detailed description of the C2R pilot.

RQ3: *How to design a method for implementing AI systems in healthcare clinics?*

The goal of **RQ3** is to get a suitable background in the domain of method engineering and to orientate on multiple method engineering methods. This will provide a model which can be used for the final method of RQ4 as context to find a suitable solution for a flexible framework.

RQ4: *How does the implementation of the designed method apply in healthcare?*

The goal of **RQ4** is to validate the method created by people more knowledgeable about the process and people who are going to use it in the future.

Each research question handles multiple topics, these topics are further elaborated upon in chapter 2. Image 1.1 displays the connections between the research questions and in which chapters the different subjects are described.

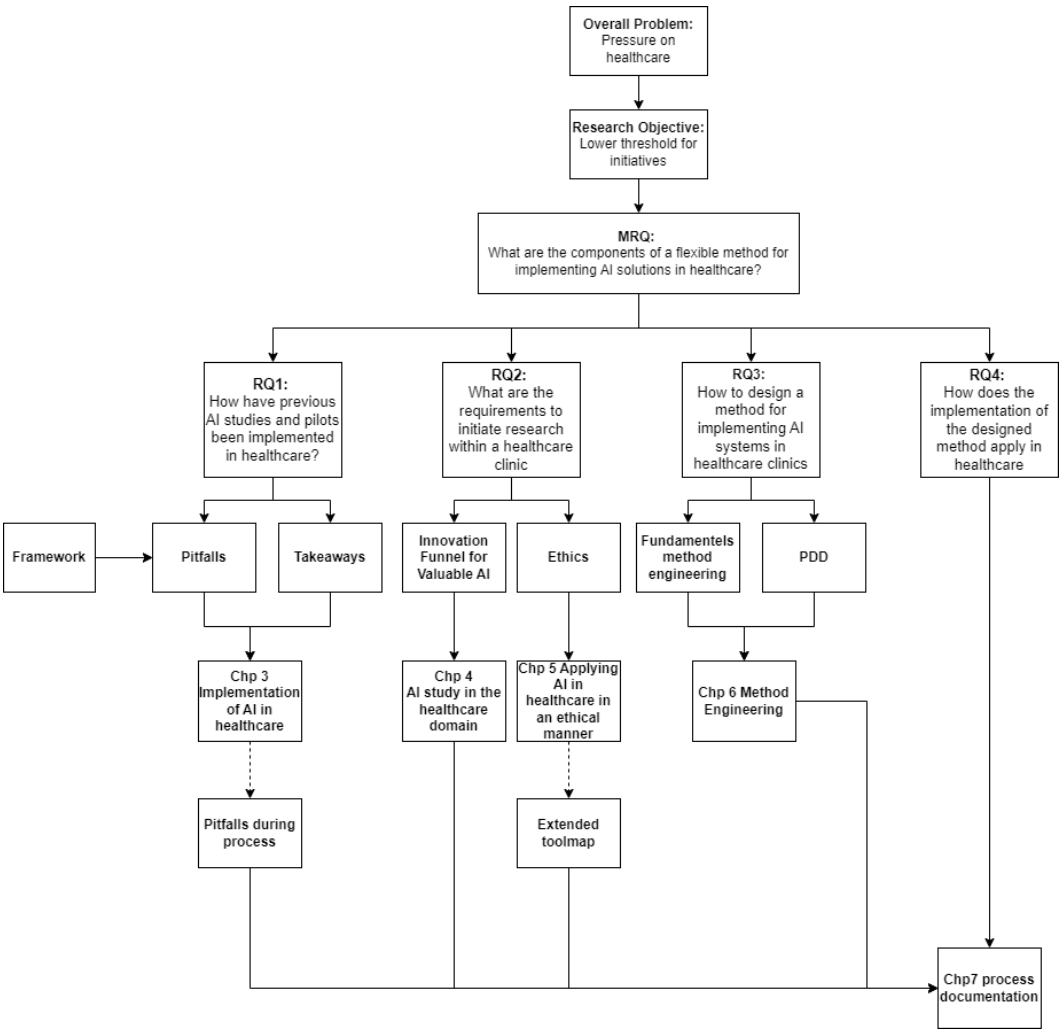

Figure 1.1: Schematic diagram of the presented Research questions

1.3 Relevance

During the COVID-19 pandemic it became clear to the public eye how much pressure there was on the healthcare system [26][24]. Not only was the healthcare system ill-suited for such events due to downscaling, lack of personnel [90] and budget cuts, but the systems which were in place were not suited for such enormous implications as the COVID1-9 pandemic.

Aiding the innovation of the current healthcare systems can help to make a healthcare expert's life easier and provide better patient care. There seems to be an urge in the healthcare landscape to innovate and use digitalize their systems [162], and although the COVID-19 pandemic has helped a great deal with normalizing the digitalization in healthcare, there is still a large amount of room for improvement [97]. Currently, Care2Report is running pilots at different clinical institutions such as research about ear infections [86]. This paper aids towards a different C2R study in which there is aimed to automatize the documentation process of the pre-operative screening (POS) phase, this study directly influences this pilot aims to help it finish successfully.

1.4 Terminology

To ensure that the terminology of AI systems is clear in the healthcare context and to remove ambiguity and add trust to the AI and the research [66], the decision is made to follow the standard set by the OECD [108] and use the term "AI system" over other, interchangeable terms. To better understand where this term comes from, and why there is chosen to follow the above standard, a description of different alternatives is given.

AI and machine learning (ML) are often used intertwined in the field [77]. However, ML is part of the broader term AI as it is one of the many techniques which use AI, just like but not limited to, deep learning, natural language processing, or supervised learning. This is why during this study the term ML will not be used as an alternative to AI.

Another alternative to AI systems that can be frequently found in the literature is AI applications. Instead of a system, which always runs in the background, an application indicates that the user must manually turn the system on. Application software often uses system software, to encompass the broad sense of AI, system fits better. [44][128].

Besides these few examples, more terms are interchangeably used in literature such as AI-based applications, algorithmic systems, automated decision-making systems, or autonomous systems[102]. But for reasons of simplicity and unambiguity, solely "AI system" is used.

Chapter 2

Research method and milestones

2.1 Research Goals

The research will aid the C2R group in different ways as a concept method will be created. There is aimed to provide structured research that will be reproducible for similar studies in the future or at other healthcare clinics which want to apply a similar strategy. Different goals have been set to which the final method has to apply. These goals have been created at the hand of the overall goal of the C2R project group.

- Flexibility

  Ensuring the method is flexible will aid the focus group in creating a standardized method that can be used in multiple healthcare clinics by using as much in place, standardized processes. This will lead to the easier implementation of the same type of method in other healthcare clinics as they are already familiar with these methods.

- Clarity

  The notation of the method should also have high clarity, as the method has to be used and understood by people unfamiliar with method engineering. The output of this study should be an easily interpretable method with no complex components, meaning it should also be understandable for people unfamiliar with the method or its notation.

2.2 Research method

This chapter describes the methods used to answer each research question.

2.2.1 Design Science

The main goal of this study is to design a method that can be used for future studies of implementing AI in Dutch healthcare. To be able to properly answer this design problem a suitable research method has to be used. This research method has to be used across different clinics but it has to be detailed enough to be prepared for the deliverables in research in healthcare. Design Science [157] is a method created for this type of research. Using artifacts that are under investigation and innovation, improvements are made to a problem in a specific context. Following the different phases engineering cycle shown in figure 2.2, artifacts and their additional problems are investigated and converted into knowledge. These cycles improve real-time research as they evaluate an implementation instead of validating a design. The research cycle and the engineering cycle are two cycles that work coherently which each other and allow an artifact to be placed in the correct context while studying the subject. At the hand of the engineering cycle 2.2, the method for doing AI research in healthcare can be designed and improved. This allows for a good alignment with the current status of the C2R focus group and a flexible study as it will enter the first pilot phase of its implementation at the UMCU.

Wieringa [156] describes four reasons to conduct research: Problem-driven investigation, goal-driven investigation, solution-driven investigation, and impact-driven investigation.

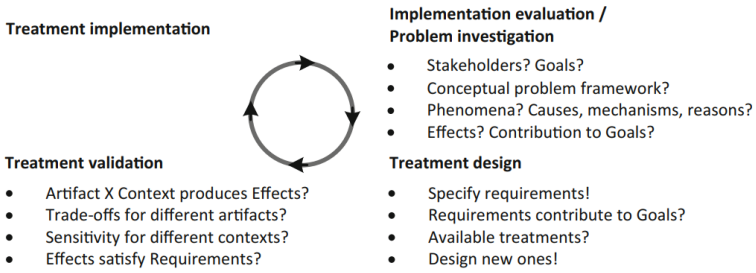

Figure 2.2: The engineering cycle by Wieringa [157]

By following the engineering cycle, the different research questions, and how they apply to the different phases in the cycle are described.

2.2.2 Problem investigation

During the problem investigation activity, **RQ1** and **RQ2** will be answered at the hand of a systematic literature review (SLR) and forward- and backward snowballing[158]. A basis of the current status of literature present will be provided Besides that, two literature frameworks have been created to further provide a basis to work upon for both research questions.

Pitfalls framework

To prevent mistakes from previous studies begin made in the future, it should be clear which mistakes have been made in the past and which pitfalls should be avoided to increase the success rate of the implementation of an AI system. To map previously made pitfalls a framework is created using of a systematic literature review [163] in a semi-structured way. This method allows the creation of a structured overview of literature at the hand of eight steps, defined in figure 2.3. In this framework, 19 different studies about the implementation

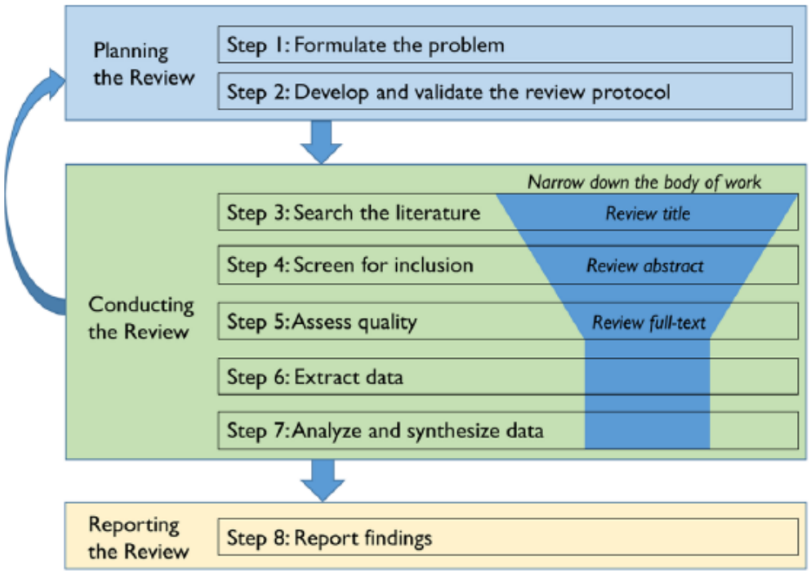

Figure 2.3: Systematic literature review process defined by Xiao and Watson [163]

of an AI will be selected using different search terms on Google Scholar and PubMed (Appendix A, table 3). These have been ordered to have the latest published papers displayed at the top. From these, the studies are filtered if they occur in Dutch healthcare. There is a large possibility that there are not sufficient papers on AI in Dutch healthcare. Whenever this is the case, the search criteria will be extended to European healthcare to keep it as close

as possible to Dutch healthcare as within Europe, many rules and restrictions within healthcare are defined by EU law, and not solely by national laws. Also, the study will be beforehand be screened if the subject is truly about artificial intelligence and not another kind of AI. For example, in healthcare artificial insemination is often also abbreviated with AI which invalidates certain search results. The found pitfalls and takeaways are categorized and included in a table for an easy overview in table 3.5. The framework maps the following qualities of the studies:

- Research source
- Search engine used
- Country of origin
- Takeaways / Pitfalls
- Takeaways / Pitfall Category

Deliverable framework

One of the main guidelines for implementing an AI system at the UMC is the Innovation Funnel for Valuable AI[100]. The Innovation Funnel for Valuable AI has over 150 deliverables (Appendix B, table B), and a proper way to document these has to be made. Also, the reader should be able to define more details from the model, so there should not only be defined what the deliverables are but also how these can be created without narrowing the scope of the entire model too much. That is why a deliverable diagram is created which allows the user to get further information on the deliverables. The table will have the same structure as the deliverables for easy lookup. The references will guide as background information or as guidelines for the deliverable and will provide a basis for the concept table for the PDD created during treatment design. The full table can be found in Appendix B.

2.2.3 Treatment design

During the treatment design activity, there is aimed to answer **RQ3**. During this activity, a literature study will be done for documenting the AI implementation process to get a better understanding of the different method engineering processes. At the hand of the takeaways and pitfalls found in **RQ1** and requirements retrieved in **RQ2**, a suitable method engineering method can be selected to create the method.

Using this method and the previously mentioned requirements and pitfalls as a basis, the method itself can be modeled and prepared for validation. As

one of the goals of this study is to be able to reuse the method for other healthcare clinics, the chosen method has to be flexible, easy to understand for people not native to the modeling language, and the method has to be able to link processes to deliverables in the implementation process of AI in healthcare.

2.2.4 Treatment validation

To answer **RQ4**, treatment validation will happen at the hand of the current C2R pilot which is currently running at the UMC Utrecht. Domain expert validation interviews will be organized to review the model. Different experts on the topic of the processes of implementing AI systems at the UMCU will be interviewed at the hand of semi-structured interviews. There will be aimed to have as many interviews until saturation is reached. Besides that, the model will be reviewed by the pitfalls and takeaways retrieved from the study of **RQ1** and analysed at the hand of an ethical review.

2.3 Threat to validity

Four different threats to validity are described by Wohlin et al. [159]: conclusion validity, internal validity, construct validity, and external validity. Using each threat to validity as a basis, the most common occurrences are described, and a short description is given of how it influences this study and how there is aimed to prevent this threat.

Conclusion validity

Conclusion validity describes the threats to validity concerning the outcome and the proposed solution. It ensures that there is a concrete relation between the measured effects of the solution and the solution itself, through the removal of chance. This often occurs whenever there is an abundance of noise in the data or a hidden bias is present. For this research, a focus group will be held to validate the final solution. This focus group consists of employees of UMC Utrecht and members of the C2R project. This could result in a biased view of the final method as these people might have their views on the implementation process. To counter this, objective questions should be asked to give a concise evaluation of the final model.

Internal validity

Internal validity includes the validity of the parts undergoing the study. It ensures that the findings are not "by chance" but are objectively grounded. This

threat to validity often occurs whenever there is compensatory equalization of treatments or rivalry but can also be caused by ambiguity about the influence of the study or statistical regression. To ensure the findings are not "by chance", both elaborated frameworks focus on Dutch healthcare. Although convenience sampling is used for the healthcare framework, to increase the internal validity the same country is used. Also, the object of study undergoes treatment by a proven method engineering method.

Construct validity

Construct validation describes the relationship between the problem described in theory and the problem encountered in practice. It can be caused by an unclear experiment design or multiple forms of bias. This study, there is aimed to keep the literature used as close to the object of study as possible. Found guidelines are solely from Dutch and European law to prevent mixups and the terminology used is the same as at the UMC Utrecht. Besides that, not only their terminology but also the same processes which the UMC Utrecht uses are used for this study as they act as a supervisor for the overall C2R project this paper is part of.

External validity

External validation takes the validation regarding generalization into account. This study focuses on the processes currently in place at UMC Utrecht. This may hinder the generalizability of the solution as some of the concepts used during the implementation process might be specific to UMC Utrecht. Unfortunately, due to the current scope of this study, this diminishment in the validity can not be mitigated. What does mitigate this threat a little, is the fact that a many laws and procedures necessary for implementing an AI system in healthcare are on the national level. This means these parts of the process apply to each healthcare institute in the Netherlands and not solely to UMC Utrecht.

2.4 Deliverables and Milestones

For this study, different milestones are set which apply. These milestones are created at the hand of the different research questions, the focus group, and pre-defined goals. The focus group's ultimate milestones differ from this study's milestones. That is why the milestones of the focus group are left out as these go beyond the milestones of this specific study. These milestones are combined with the timeframe described in figure 2.4.1

- RQ1: Finished and fully described pitfalls framework
- RQ2: Finished literature study about method engineering
- Long proposal finished
- Long proposal presentation
- RQ3: Deliverable framework finished and fully described
- RQ4: Draft method created
- Draft method reviewed
- Final method created
- Final thesis finished
- Thesis defence

2.4.1 Timeframe

This study will take place over the course of thirty weeks. The first ten weeks will be dedicated to preparing the pilot research at the UMCU and finding background literature. The final twenty weeks will be dedicated to modeling, finishing the study, and validation.

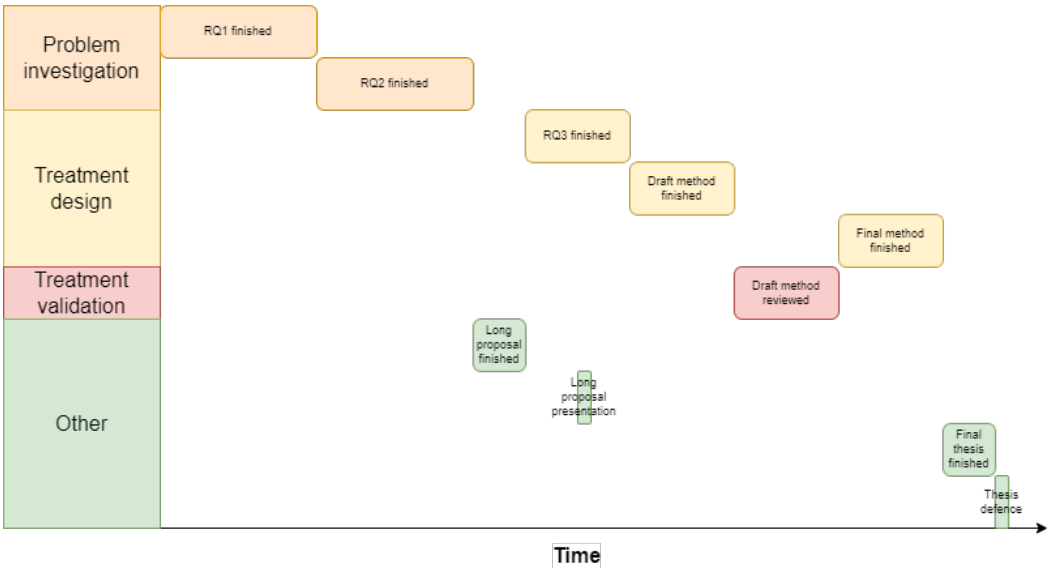

Figure 2.1: Study milestones and planning

Chapter 3

Implementation of AI Systems in Healthcare

This chapter describes different studies about applying automatization in different healthcare projects. The goal of this chapter is to describe the different pitfalls and takeaways found during the literature study summarized in the pitfall framework, described in chapter 2.2.2. The following studies have been found (table 3)

Table 3.1: APA references to the corresponding literature found

Reference	**APA**
[145]	van der Meijden, S. L., de Hond, A. A., Thoral, P. J., Steyerberg, E. W., Kant, I. M., Cinà, G., & Arbous, M. S. (2023). Intensive Care Unit Physicians' Perspectives on Artificial Intelligence–Based Clinical Decision Support Tools: Preimplementation Survey Study. JMIR Human Factors, 10, e39114
[141]	van Baar, R., Spruit, M. R., & Verberne, S. Bachelor Informatica & Economie
[67]	Grünloh, C., te Braake, E., Hurmuz, M., & Jansen-Kosterink, S. Balancing data-hungriness of AI and the workload of manual data collection. Trust, Professional Vision, and Diagnostic Work. 19, 28
[46]	Busuioc, M. (2022). AI algorithmic oversight: new frontiers in regulation. In Handbook of Regulatory Authorities (pp. 470-486). Edward Elgar Publishing
[146]	van der Zander, Q. E., van der Ende-van Loon, M. C., Janssen, J. M., Winkens, B., van der Sommen, F., Masclee, A. A., & Schoon, E. J. (2022). Artificial intelligence in (gastrointestinal) healthcare: patients' and physicians' perspectives. Scientific Reports, 12(1), 16779

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Reference	APA
[57]	de Vos, J., Visser, L. A., de Beer, A. A., Fornasa, M., Thoral, P. J., Elbers, P. W., & Cinà, G. (2022). The potential cost-effectiveness of a machine learning tool that can prevent untimely intensive care unit discharge. Value in Health, 25(3), 359-367
[147]	van Mens, K., Elzinga, E., Nielen, M., Lokkerbol, J., Poortvliet, R., Donker, G., ... & de Beurs, D. (2020). Applying machine learning on health record data from general practitioners to predict suicidality. Internet Interventions, 21, 100337
[56]	de Korte, M. H., Verhoeven, G. S., Elissen, A. M., Metzelthin, S. F., Ruwaard, D., & Mikkers, M. C. (2020). Using machine learning to assess the predictive potential of standardized nursing data for home healthcare case-mix classification. The European Journal of Health Economics, 21, 1121-1129
[70]	Huberts, L. C., Does, R. J., Ravesteijn, B., & Lokkerbol, J. (2022). Predictive monitoring using machine learning algorithms and a real-life example on schizophrenia. Quality and Reliability Engineering International, 38(3), 1302-1317
[42]	BOSMAN, C. A DOUBLE MACHINE LEARNING APPROACH (Doctoral dissertation, tilburg university)
[58]	De Vries, B. C. S., Hegeman, J. H., Nijmeijer, W., Geerdink, J., Seifert, C., & Groothuis-Oudshoorn, C. G. M. (2021). Comparing three machine learning approaches to design a risk assessment tool for future fractures: predicting a subsequent major osteoporotic fracture in fracture patients with osteopenia and osteoporosis. Osteoporosis international, 32, 437-449
[153]	Wardenaar, K. J., Riese, H., Giltay, E. J., Eikelenboom, M., van Hemert, A. J., Beekman, A. F., ... & Schoevers, R. A. (2021). Common and specific determinants of 9-year depression and anxiety course-trajectories: A machine-learning investigation in the Netherlands Study of Depression and Anxiety (NESDA). Journal of Affective Disorders, 293, 295-304
[36]	Averbuch, T., Sullivan, K., Sauer, A., Mamas, M. A., Voors, A. A., Gale, C. P., ... & Van Spall, H. G. (2022). Applications of artificial intelligence and machine learning in heart failure. European Heart Journal-Digital Health, 3(2), 311-322
[37]	Bakkes, T., van Diepen, A., De Bie, A., Montenij, L., Mojoli, F., Bouwman, A., ... & Turco, S. (2023). Automated detection and classification of patient–ventilator asynchrony by means of machine learning and simulated data. Computer Methods and Programs in Biomedicine, 230, 107333

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Reference	APA
[133]	Strohm, L., Hehakaya, C., Ranschaert, E. R., Boon, W. P., & Moors, E. H. (2020). Implementation of artificial intelligence (AI) applications in radiology: hindering and facilitating factors. European radiology, 30, 5525-5532
[120]	Sangers, T. E., Wakkee, M., Moolenburgh, F. J., Nijsten, T., & Lugtenberg, M. (2023). Towards successful implementation of artificial intelligence in skin cancer care: a qualitative study exploring the views of dermatologists and general practitioners. Archives of Dermatological Research, 315(5), 1187-1195
[129]	Stegeman, R. (2022). The reality of Dutch AI implementation (Bachelor's thesis, University of Twente)
[75]	Koolstra, D. (2020). The (un) desirable patient decision support technology in Dutch healthcare: A case study of the perceived adoption climate for health decision technology in The Netherlands
[62]	Floruss, J., & Vahlpahl, N. (2020). Artificial Intelligence in Healthcare: Acceptance of AI-based Support Systems by Healthcare Professionals

The different findings are summarised so they can be taken into assessment during the modelling of the implementation process of an AI system in healthcare. In table 3 an overview is given of which terms are used for finding the literature and how many were used. The full table with takeaways and pitfalls can be found in appendix A table A.

Table 3.2: Search and the number of literature used after the exclusion criteria

Search string	Hits
AI dutch healthcare	5
"machine learning" AND "Dutch healthcare"	6
"machine learning" AND "healthcare" AND "Netherlands"	3
"artificial intelligence" AND "Dutch healthcare"	5

Table 3.3: Sources, search engine & country of origin

Reference	Site	Origin	AI	Medical Domain
[145]	GS	NL	AI Clinical decision Support	Intensive care
[141]	GS	NL	ML (NLP)	Elderly care
[67]	GS	NL	AI in general	Diverse domains
[46]	GS	NL	AI in general	Diverse domains
[146]	PM	NL	AI in general	Oncology
[57]	GS	NL	ML	Intensive care
[147]	GS	NL	ML	GP
[56]	GS+PM	NL	ML (random forest)	Home healthcare utilization
[70]	GS	NL	ML	Diverse domains
[42]	GS	NL	Double ML	COVID-19
[58]	GS	NL	ML	Trauma Surgery
[153]	GS	NL	ML (cross-validation)	NESDA
[36]	PM	UK	ML	Cardiac Disease
[37]	PM	IT	ML	Intensive care
[133]	GS	NL	AI in general	Radiology
[120]	GS	NL	ML (Deep Neural Networks)	Dermatology
[129]	GS	NL	AI in general	Diverse domains
[75]	GS	NL	AI Clinical decision Support	Diverse domains
[62]	GS	GE	AI in general	Diverse domains

3.1 Results Systematic Literature Review

In the 19 papers reviewed, the following categories of pitfalls and takeaways retrieved from the systematic literature review have been found 3.5. These can be categorized into three different themes:

- Willingness of working with AI systems
- The AI black box
- Data Gathering

As can be deduced from this, a broad spectrum of different takeaways can be made from this. However, some topics are addressed in more papers than others. This is due to the goal of the papers themselves and the importance of the subject in AI system implementation. First of all, the willingness of healthcare experts to adopt AI has been addressed in eight studies. This can be explained, as it is an important aspect of implementing an AI system in

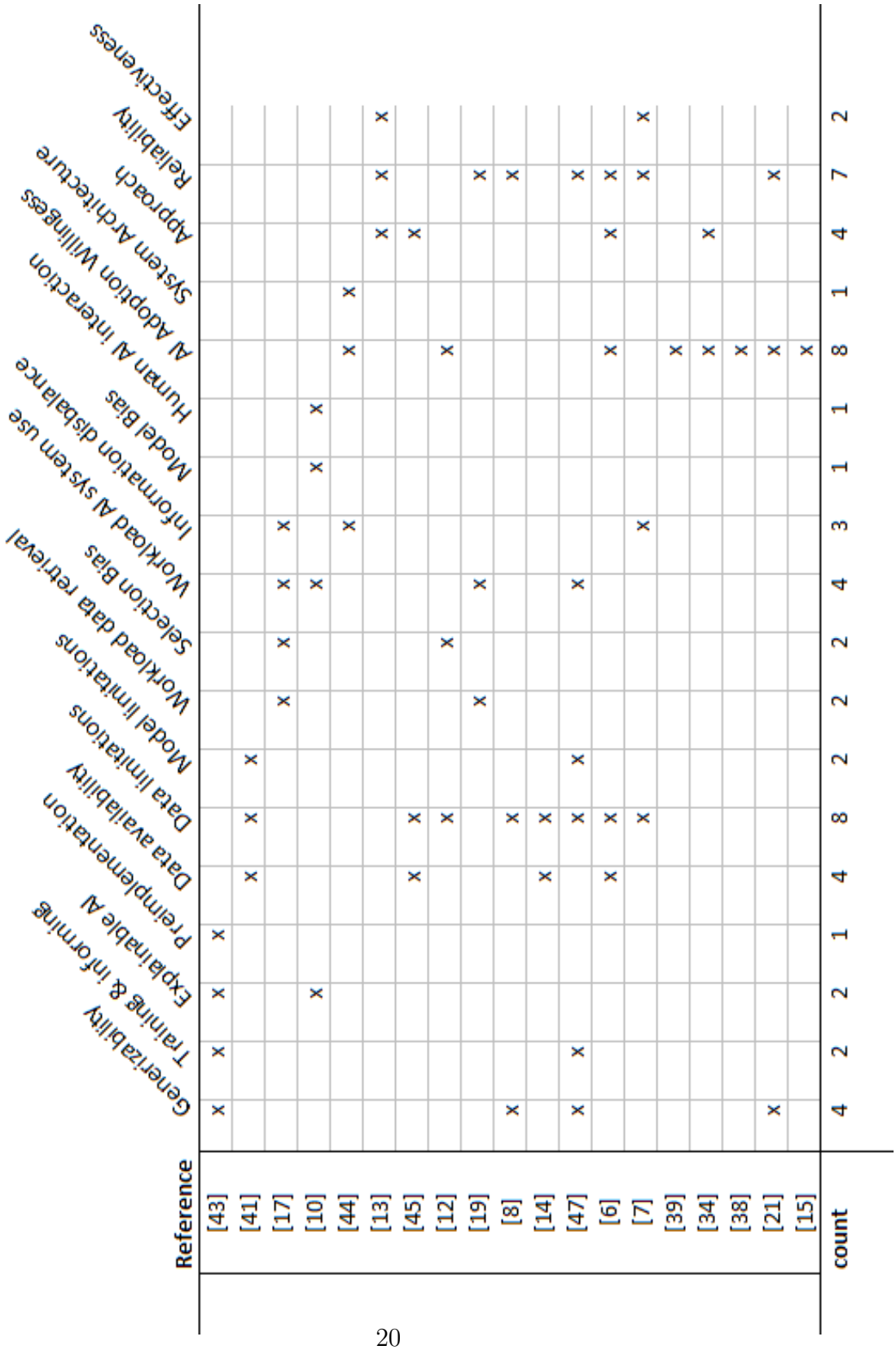
healthcare; how willing healthcare experts are to participate in these cases can make or break a pilot.

The concern for data limitations is also addressed in eight studies, data was often not immediately fit for the AI system and had to be transformed to be made fit. This also affected the reliability of the AI system, which was addressed in seven cases. Having limitations in the data can affect the reliability of the AI system and its algorithm. These limitations can also be explained by the availability of the data, which was addressed in four studies. In each study a pitfall was discussed about data availability, also a pitfall about data limitation was addressed. The other categories did not feature a prominent number of times.

Table 3.4: Categories of pitfalls and takeaways categorized by theme

Theme	**Category**
The willingness of Working with AI	Human AI interaction
	AI Adoption Willingness
	Training & informing
	Workload data retrieval
	Information disbalance
	Workload AI system use
The AI Black Box	Explainable AI
	Preïmplementation
	Model limitations
	Model Bias
	System Architecture
	Approach
	Reliability
	Effectiveness
Data Gathering	Data availability
	Data limitations
	Selection bias

Table 3.5: Number of times certain findings occurred in the SLR



3.2 Willingness of working with AI

The willingness to adopt AI systems in healthcare has both supporters and detractors. As AI is a relatively new subject in our world it might be thought of as an unnerving endeavor on how it will influence the working environment in healthcare. Especially when combining this with a new method in an already scientifically proven process. The current healthcare workers are key for the acceptance of the AI system as if a majority of clinical experts use a system, it increases the willingness of other experts to implement such system [62]. Still, there is a high willingness to participate in research-related tasks [107] [146] for implementing AI systems in healthcare. Healthcare experts gladly contribute to new scientific processes such as running pilots or cooperating in the data gathering process. The willingness of healthcare workers and their patients depends on their age, speciality/healthcare clinic, and their familiarity with AI [146]. However, it differs per research on which characteristic this willingness to adopt depends on.

The differentiation in acceptance rates between different ages, departments, and the familiarity of AI might be due to the diffusion of innovation [74]. People adopt innovations at different rates. As AI systems are a relatively new subject within healthcare, only innovators and early adopters currently have adopted the idea of implementing AI systems in healthcare. Over time, the willingness to adopt AI systems will improve as the more people use a certain system, the more willing people are to accept this system [62].

As the implementation of AI systems in healthcare can have many advantages, it must be known how to improve the acceptance rate of AI systems and why certain thresholds exist for healthcare professionals. Increasing different factors such as, but not limited to, transparency and validation lead to a better acceptance rate [120] by healthcare professionals. The Dutch government even has financial funds available for piloting AI systems that can be used by its citizens [129]. There are some concerns that AI systems might replace jobs in the healthcare sector [133]. Although this might not seem like a very realistic future for AI systems in the healthcare sector. The acceptance of an AI system is dependent on the way it influences the process itself. The AI system should be advisory to the healthcare provider, not dictating [75]. This will result in AI systems in early development phases will not stand in high regard and retrieve cooperation in early development and implementation phases.

3.3 The AI black box

Healthcare experts rather have an AI system in an advisory role than in a dictating manner. Potentially, this is caused due that AI systems can be complex, especially for people without a background in computer engineering

or AI. This lack of knowledge can result in an AI system that seems like a 'black box' [46][153]. This implies that for clinical experts, data goes into the system but then an unknown process takes place, on which the expert does not have any influence and does not know what happens, and a decision comes out.

How an AI system works is important to the people who have to use the system. People in the medical field are highly knowledgeable about why certain decisions have to be made, and knowing how an AI makes decisions is important for them to improve trust in the application they are using [145].

To be able to prevent an AI system from becoming a black box, the AI system has to be explanatory. An explanatory AI system is designed to make it easy to understand for a user to understand what the AI system does. Transparency of how the AI system works can lead to a better acceptance rate [133] of adoption of AI systems. Part of this transparency can be the accuracy and the risk of health inequalities of the use of the AI system [120]. By addressing these aspects of the AI system, a healthcare expert can act upon these weaknesses when deemed necessary. Another way to improve the willingness to adopt an AI system is that an AI system should have evidence that is it value-adding [133][56]. This is also an important feat as newly implemented AI studies might not live up to their full potential in the early stages of implementation. Applying an AI in the wrong clinical stage leads to less added value or not even being able to draw conclusions at all [147]. For instance when an AI system is trained to recognize appendicitis but is trained on data of patients with acute appendicitis. This will result in that a large number of cases will be neglected by the system as the symptoms of acute appendicitis are more extreme than in regular cases. Implementing the AI in all clinical stages can help with measuring the effectiveness of the AI [57] and thus find the best stage the AI applies to.

3.4 Data Gathering

Data retrieval is a vital part of the AI system implementation process. Unfortunately, in healthcare data is often not readily prepared for use in AI systems. Not enough data is available, or the available data is limited. In the current healthcare system, the data present is not fit for immediate implementation in an AI system but first has to go through data transformations [36]. This can result in that certain necessary details being unavailable for the AI system, resulting in that, not the right conclusions can be derived with the AI system [58] [42] [141].

Having incomplete, incorrect, or missing data leads to a less effective AI system [36]. It should be clear during the data retrieval that no unwanted bias is supported [46]. Such bias can negatively affect certain groups in society

or allow for an informational disbalance between healthcare experts. Besides that, if another data retrieval method is used instead of using the healthcare systems already in place, no pre-emptive direction should be given to it. This can influence the questionees in giving certain answers. This can lead to a bias and useless training data [67].

Although the already present data sources might not be ready for direct implementation in an AI system or the data set might not be complete, it can be filled using another AI system to keep up the performance [36]. There should be taken into account that processing the data sometimes can not be done in real-time depending on the transformation methods and the system architecture used [37]. Data transformation is exhaustive and very process-heavy [70] which unfortunately, due to the many cases of unfit data present, seems almost mandatory. Streamlining the infrastructure to the needs of the AI might help its effectiveness to make sure this process takes as few resources as possible [146]. Also, having a standardized use of terminology could increase the feasibility [56]. A standardized terminology leads to fewer exceptions which can make the process of implementing an AI system less complex. But even if the data is fit for use in an AI system, a data shift may happen to reduce the effectiveness of the AI system [36]. A data shift occurs whenever over time the training and test data are no longer viable with each other. For instance, data can become no longer viable over time as symptoms or medicine changes. A data shift can result in a less precise AI system, something which is not wanted in the healthcare environment.

3.5 Chapter Summary

This chapter describes a SLR aimed to provide an overview of previous made pitfalls and takeaways. At the hand of this SLR, three different themes have been found, at the hand of which, the different pitfalls and takeaways have been described.

Chapter 4

AI study in the healthcare domain

Introducing an AI system at the UMCU Utrecht is an extensive process as a substantial number of measures have to be taken into account to conduct ethically correct and safe research. First of all, there has to be adhered to the different processes in place at the UMCU. Next to that, the development and study done for the AI system apart from the UMCU have to be done in an ethically correct manner as well. This chapter describes the processes in place at the UMCU for implementing an AI system and secondly, different pitfalls to take into account and things to keep in mind for doing ethically correct research.

4.1 Processes University Medical Centre Utrecht

Implementing an AI system at the UMCU is supervised by the Digital Health department. The Digital Health department at the UMCU is a department instituted for the development and implementation of digital innovations. The employees of the digital department position themselves as data analysts for the UMCU and as project managers for initiatives started at the UMCU and will from now on be referenced as Digital Health. For assisting external researchers in the UMCU, the UMCU has developed the Innovation Funnel for Valuable AI in Healthcare [100](figure 4.1). The Innovation Funnel for Valuable AI in Healthcare consists of seven phases, in which in each more value is added to the method. The seven phases are:

1. **Idea** *Elaboration of the problem and checking how a solution might look.*

2. **Exploration** *Research requirements, required resources, and possible solutions.*

3. Development *Start development of the AI system.*

4. Pilot A *Run a pilot with test data and evaluate.*

5. Pilot B *Run a first clinical test and evaluate.*

6. Implementation *Implement the AI system in practice.*

7. Use *Monitor the AI system while implemented.*

However, in this funnel, Digital Health does not track the progress of the initiatives. At the hand of different project reports, they check whether different criteria are met. This is done using Zenya [1].

4.2 Zenya Templates

In the Zenya environment of Digital Health, the different phases and templates are collected and structured. At the hand of each phase described in the Innovation Funnel for Valuable AI in Healthcare, each phase is described at the hand of a short explanatory note, templates that can be downloaded for tracking (such as the project reports), and further articles which can aid the initiatives. Besides the same phases as in the Innovation Funnel for Valuable AI, two different groups are used for structuring these phases; the develop/buy, and use groups. In the use group, the implementation and use phases are present, while in the develop/buy all prior phases are present.

[1] https://zenya-software.com

4.3 Innovation Funnel for Valuable AI in Healthcare

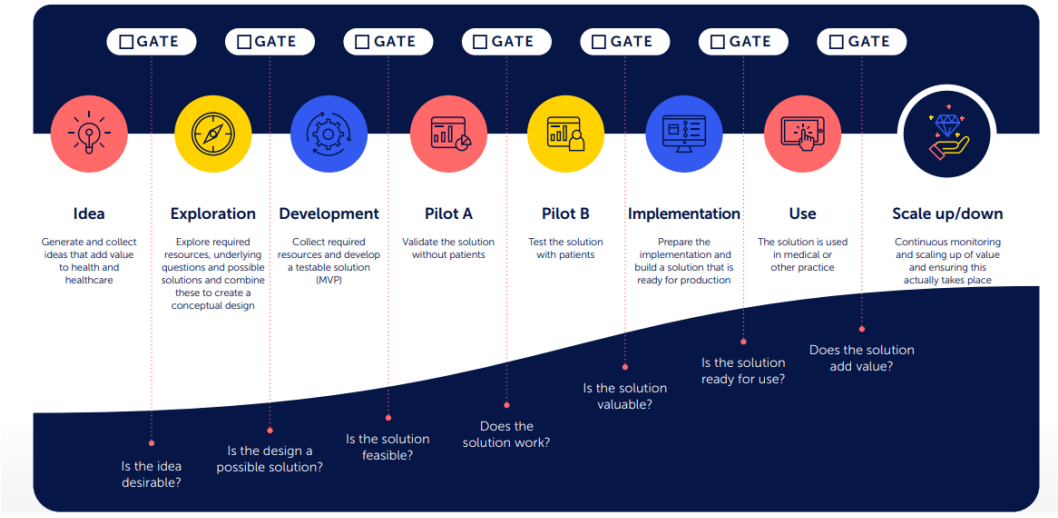


Figure 4.1: The Innovation Funnel for Valuable AI in Healthcare [100]

In the transition of each phase, there is a gate where is decided whether the study may continue. A gate consists of multiple deliverables which have to be judged by a certain actor. Dependent on the phase, these actors and deliverables differ. The decision on whether the study can continue towards the next phase is summarized in a project report. The deliverables of each gate are divided into five different domains. The five domains used are:

- Value
- Application
- Ethics
- Technology
- Responsibility

4.3.1 Domains

First, a background will be given to each domain to provide further background to the goal and the origin of the deliverables.

Value

The value of an AI system describes the added value for or the impact the method has on the patient and the nurse/doctor. For the AI system to have a positive impact on patients is of great importance. However, some AI systems do not have a direct effect on the patient but can still have a positive impact on them. For example, whenever an AI system reduces the time nurses have to spend on documentation, allowing them to help more patients and thus, reducing waiting times for patients. During the different phases, the value and impact of the AI system are monitored to ensure that the impact on patients stays as expected and is approved and above an acceptable threshold. To measure the value of an AI system, multiple methods can be used, such as [154]: cost-benefit analysis, cost-effectiveness analysis, cost minimization analysis, social cost-effectiveness analysis, social business case, social return of investment, budget impact analysis, or multi-criteria analysis. Each method has its pros and cons and should be chosen dependent on the situation or which phase the AI system is in during the innovation funnel. To chart the impact of an AI system also a more complete method can be used such as the prescribed artificial intelligence impact assessment [151] or the AI routemap[1][2] to measure the maturity of the AI method used.

Application

The application domain of an AI system in healthcare elaborates more on the functionality and the idea behind the implementation of the AI system. This can range from the prototype to creating user stories[52] or measuring the user experience. Designing software for healthcare works differently than designing regular software applications in the B2B or B2C domain. Designing and implementing software for healthcare should apply to higher standards than software made for commercial purposes [134]. During regular software development often the implementation comes first, and then there is a check if it works. Using this method in healthcare can lead to disastrous consequences if the software does not work correctly yet. Wrong calculations or bugs can lead to wrong treatment. The software can guarantee these standards by applying to different ISO standards specially made for healthcare [72][53]. These standards can prove that the software made for healthcare upholds a certain standard and has been tested properly.

Ethics

Implementing AI systems in healthcare in an ethical way is an important aspect of the design of the software. To be able to train the algorithm of an AI system objectively and correctly, an ethical review should take place. Having

a misguided, or inconclusive algorithm is one of the most occurring mistakes in AI in healthcare [103]. Besides that, AI systems can choose an unfair outcome for certain groups or allows for traceability. All of this can happen on multiple levels of abstraction within the software development process. One of the ways to properly take the context of an AI system into account is by setting up cases and mapping different factors which apply to this case such as actors, values, and effects of the AI system in the current context [98]. These can be used to get a better understanding of the technology needed, the ecosystem the AI system is used in, and how the AI system is used. To ensure all the context is properly taken into account, different steps can be undertaken [99]:

1. Centralize public values
2. Involve stakeholders
3. Respect laws and other obligations
4. Beware software security
5. Release bias from data, algorithms, and analyses
6. Be transparent and accountable
7. Monitor, evaluate, and adapt

In chapter 5 a further elaboration about doing ethical research and implanting AI in healthcare in an ethical manner is further elaborated.

Technology

The technology domain describes the innovation of the AI system which is introduced in the study. First, there has to be deducted if the AI system and the underlying software can be seen as a medical device. This can be done at the hand of the infographic by the European Commission [29] in which in five steps there can be decided whether the software is covered under the law by medical device regulations or not. Medical devices fall under different regulations than regular technology and have to go through multiple assessments by the METC before they can be fully implemented [93]. Besides that, correct cyber security protocols have to be in place for AI systems. Trustworthy AI systems allow for better adoption by healthcare experts, creating a trustworthy AI landscape and keeping an eye on the different challenges and benefits of this [12]. Data can be retrieved from many places, and for each source the trustworthiness should be taken into account, keeping an eye on pitfalls and focus points [9]. A great way for checking the completeness of an AI system in the clinical trial process is by using an existing AI extension [118][84]. This can also be done for preventing bias in an AI system [161].

Responsibility

In the responsibility domain, accountability is taken into account. This not only is described who is accountable for each aspect of the implementation and creation of the AI system but also for activities that stakeholders have to take such ask risk analyses. With the recently strengthened legislation [8] the implementation of new AI systems must be done correctly. Correct agreements have to be made between the hospitals, users, and suppliers on who is responsible for which parts of the system, how feedback is best given, and how data is saved [9]. A service legal agreement is a great way to encapsulate the responsibilities of the different users and providers of the AI system [16]. In this agreement, different agreements can be made about subjects such as system downtime and help desk availability. Using a predefined checklist from the field can be a great way to define all subjects in the SLA. For example, Kader has established a checklist for healthcare with twelve points that have to be taken up into the SLA for a complete document [73].

4.3.2 Phases

In the next section, each phase of the seven phases model will be further elaborated. In each section, the goal of the phase is elaborated at the hand of each domain. Besides that, the different activities and deliverables are described. The different deliverables as found in appendix B are highlighted using italics and can be found on the right side of the text for recognizability.

Idea

In the idea phase, ideas can be proposed or accumulated by the research team at the healthcare institution. The ideas are brought forthcoming from different issues within different processes in the hospital. The ideas have to be problem-orientated to ensure no tunnel vision is created from the design perspective. Otherwise, this can lead to a predetermined solution that might not be the best.

The *idea description* is presented using the SCQA method, in which the situation, complication, and question are described. A first solution is sketched and alternative ideas are described. During this first phase, the *potential stakeholders* and the end user are determined. Together with the total *life-cycle* of the potential solution, a business case is set up for the issue. Besides that, the potential *tangible value* is described, together with the potential impact the solution might have at the hand of a first *impact analysis*

idea description

potential stakeholders

solution life-cycle

tangible value

impact analysis

To get a better understanding of the current situation the current process is described for future reference at the and of a *process exploration*. Besides

process exploration

that *personas* are created to get a better understanding of the current end user. To see if the idea is feasible, there also has to be determined whether there is enough *data available* for an AI system to be implemented, if so, there has so to decide whether the required AI system will be bought or developed in-house. At the hand of this, an *impact analysis* is done to identify what the costs, infrastructure, etc. needs are for the system.

personas

data availability

impact analysis

A *strategic ambassador* has to be appointed to hold accountable for the project, besides that the *feasibility* of the project has to be assessed and the *conditions* under which the project is done have to be decided upon. This is done at the hand of an initial *risk scan* and a data protection impact assessment (*DPIA*). If there are any external partners in the projects, *contractual arrangements* have to be made.

strategic ambassador

feasability & conditions of responsive use

risk scan

DPIA

contractual arrangements

Besides the risk analysis, multiple *impact analyses* have to be done to see if the impact of the study is proportional to the negative societal effects of the project and if affects different stakeholders *equally*. Besides that, there has to be checked if the assessed end user is viable to use the final product when thinking about the role, skill level, and other factors. Finalizing the phase, *guidance ethics* have to be taken into account to specify the influence the AI system can have on the organization.

impact on society

impact on healthcare

impact on inequalities

guidance ethics

Exploration

The exploration phase continues on the ideas which passed the gate of the idea phase. These refined ideas are further explored, especially the solution aspect of the idea, and are further elaborated in this phase.

To assess the potential value, different *research questions* have been set up. A *stakeholder analysis* has to be done and at the hand of these different stakeholders and research questions, *user stories* have to be created. To be able to create a *business case* and do a *market scan*, the potential solution has to be valued and compared at the hand of a market scan to competing solutions. From this, a *valorization strategy* can be created which aims to convert the knowledge retrieved from the business case.

research questions

stakeholder analysis

user stories

business case

market scan

valorisation strategy

To further describe the product, a *patient journey* has to be created to gain insight into how the AI system interacts with the workflow of the solution. Together with a *prototype* of the solution, a *development plan* can be made. A *data end report* can be created, describing the necessary data for the AI system to work. A beginning has to be made of the *system architecture*.

patient journey

prototype solution

development plan

data end report

system architecture

For accountability, a *liability analysis* has to be made. At the hand of this

liability analysis

analysis, there has to be decided whether the AI system is a *medical device*. Medical devices have higher risks and need possible certifications, something which also has to be determined by the chosen manufacturer of the software the AI system uses. Thus also a *risk management plan* has to be made. In this plan, different acceptance criteria are picked up. Part of this analysis is a *risk-benefit analysis* which has to come out possible for it to be possible to further continue with the project. Besides this, the *DPIA* has to be extended by removing *non-vital data* for the system and introducing *data aggregation*. When the AI system is developed by a third party, the *determined manufacturer* has to be assigned. Beforehand, a *clinical evaluation plan* has to be set up for later stages. To finalize the accountability, an *information security risk assesment* has to be done to check the vulnerabilities

medical device assesment

risk management plan

risk-benefit analysis

data minimization & aggregation

determined manufacturer

clinical evaluation plan

information security risk assesment

At last, the total design of the project has to undergo an analysis of the *ethics of the design* to check whether the actions taken by the users are ethically correct. Besides that, *proof of consent and autonomy* has to be created for patients who participate in the pilots and later stages of the project. Finally, there has to be documentation about the impact of AI system on the daily lives of the end users, stakeholders and, the operating system and exploration is necessary of the *required support* for users who have to work with the system.

ethics by design

proof of consent & autonomy

required support for acceptable human interaction

Development

During the development phase, the *finalized idea* is produced. This can mean two things, an existing application has been tuned to the needs elaborated in the idea and exploration phase or an entirely new AI system has been custom-made. These are aimed at the needs of the predefined stakeholders and the value which needs to be added to fix the problem identified. This product has been demonstrated at the hand of *demos* to the client, partners, and fundraisers. At the hand of these demos, the *business case* is updated.

developed AI system

demos of MVP

To be able to have the user properly use the application, first different *personas* have to be created. At the hand of these, *expert sessions* can be organized and ambassadors for the application are appointed. The *user interaction and user experience* have to uphold to a certain extent and proper *training* for the use of the application has to be created.

personas

expert sessions

UX & UI requirements

training

For proper data management, *data collection* and storage methods have been provided. These include a *data model* that facilitates the interoperability of these methods. Besides this, an *architecture map* is necessary for the processing of this data and the definitive version of the *AI algorithm* which is in use. This all has to come together in a functional *minimal viable product*, ready for the second phase; Pilot A.

data collection, model, & repository

architecture map

Definitive algorithm

functional MVP

To uphold the accountability of the application, it has to be given a definitive *risk class*, at the hand of which, its use has to be verified whether it falls within proper limits. For information security, a separate risk class has to be assigned. Besides that, a start has to be made for the *certification* process of the application. The previous *risk management plan* has to be updated and a new *risk-benefit analysis* has to be done at the hand of residual risks. At the hand of this, the *DPIA* can be updated for the next phase. If data is handled outside of the institution, data protection agreements have to be made. A *clinical evaluation report* has to be made with a plan to improve the technical performance of the application. Finally, a start has to be made with the *investigational medical device dossier*(IMDD).

risk class

certification plan

clinical evaluation report

IMDD

To ensure ethical development, there has to be analyzed whether the application is currently according to the *norms and values* of the clinics' practices. Besides that, the application should allow for a *great degree of freedom* for the user, and allow it to have a large amount of insight into the decisions and values. This should also be checked at the hand of a *due diligence checklist*. Besides the level of transparency, the sensitivity of data in use and storage, and the way errors are handled (both in the application and medical treatment) have to be checked at the hand of a due diligence checklist.

verification of norms and values

Application respects user autonomy

duediligence checklist

Pilot A

During the first pilot phase, there is checked whether the solution works in a controlled environment. Doing this can help improve the solution, find flaws, and make other changes.

The tested AI system has to be *presented to different stakeholders* such as funders or potential partners to present the *added value*. After this, a *validation plan* is made and ready to be used in a real-world environment in pilot B. An overview of the *available financial resources* has to be made, allowing for an update of the *business case*. During this time feedback has been retrieved from future users by holding expert sessions and the UI and UX have been evaluated. An *incentive analysis* is held which will be validated in the next phase, during this analysis different aspects are taken into consideration: performance expectancy, effort expectancy, social influence, and facilitating conditions. To measure this, *expert sessions with users* can be held, which allows for a *UI evaluation* and different *training & schooling* to be in place.

demos of AI system

added value

validation plan

available financial resources

incentive analysis

expert sessions

training & schooling

For the technology of the AI system, this means that the *data storage* and transformation are available in the environment that will be used next phase. It also means the system is *scalable* and the *definitive AI system* is finished.

data storage

scalable development environment

definitive AI system

To uphold the accountability of the application, *governance agreements* are made with *external partners* and must allow for safe and reliable use of the application. At the hand of the results of the pilot, the *risk management plan* and the *DPIA* have to be updated. Besides that, the *clinical evaluation* report has to be updated with the technical performance of the application. For information security, a special *risk classification* must be done and the *definitive version of the IMDD* must be prepared for pilot B. To allow real-time patient tests, the *WMO classification* has to be finished. Finally, a *privacy statement* must be made for use during pilot B.

governance agreements with external suppliers

WMO classification

privacy statement

To ensure the pilot is done in an ethical matter, a *validation list* has to be created with the expected consequences of using the application in the next phase. The previously created *impact analysis* has to be recalibrated and a list of *stop criteria* has to be made for pilot B which can be monitored during the process. The *informed consent form* has to be created and ready for use at the start of pilot B. Finally, any *unwanted functions* have been considered and removed.

validation list

social & societal impact analysis

stop criteria

informed consent form

function creep

Pilot B

During the second pilot phase, the AI system is tested on real patients. During this phase, there is checked whether the solution is viable in a real-life situation. Here can be checked if the *added value* weighs against the original expectations. There can be checked whether the final *AI system is accepted* by patients, users, and stakeholders. Besides that, a first look has been taken into the *possibilities to scale up*. The total value of its application is measured at the hand of a *cost/benefit analysis*, and the business case has been refined, which can optionally be part of a Health Tech Assessment (*HTA*). Also, there has to be checked whether the *stakeholders* are still relevant, or that new relevant stakeholders have come into the picture.

accepted AI system

scale-up check

cost-benefit analysis

HTA

On the application level, the *operational and social effects* of the AI system have been measured. At the hand of the *expert sessions* held, feedback is processed and the *UX and UI* have been measured. The different *needs in training* for each user has been determined and *changes in the protocol* have been determined. Also, the *definitive data storage* has to be up and running and has to adhere to the data standards.

operational & social effects of use

expert sessions

UI & UX measurements

Training needs

changes of protocol

A *final risk-benefit analysis* has to be done and the residual risk determined during pilot B has been added. The *DPIA* has been updated with the data used in a training context. The IMDD must be converted to a *product*

dossier. The*clinical evaluation report* has been to be updated at the hand of the technical performance and clinical evaluation. Finally, a *risk classification* has to be made for information security.

information security risk classification

At last, an *ethical analysis* has been done to prevent overburdening the end user by checking the risks, work pressure, and emotional burden. Also, there has to be assessed what effect the use of the application has on the *relationship* between the patient and the healthcare provider. Besides that, the *scientific effect* of the application has to be assessed and assumed as sufficient. Finally, there has to be checked whether there is no *unwanted functionality*, and if there is, it has to be removed.

proportionality analysis

effects on relationship

broader scientific application

Implementation

During the implementation phase, the final AI system is created and made ready for implementation in the real world. For the AI system to be ready for use, a *description of the utility* it provides and the need it fulfils needs to be further elaborated to investors and society at the hand of another *stakeholder check*. It must be sure that *no changes* have taken place after pilot B so no changes in value could have taken place. This is important for dividing the different costs and benefits across stakeholders. The *definitive business case* must be finished and the conditions to use the final AI system must be clear and *funding* in place. Also, there must be different *measuring and monitoring systems* in place for the final phase.

social returns

no functional changes check

funding

measuring & monitoring systems

For the AI system itself, there must be an *implementation plan* for each of the target stakeholders. There should be sufficient *information and promotion* available to educate the users and other stakeholders. The AI system should *meet standards* set by healthcare and other certifications and succeed in the *acceptance tests*. For the AI system the users should be *trained*, there should be *manuals*, and *procedures* for the safe use of the system, and *functional management and support* should be available.

implementation plan

information & promotion

AI system meets functional standards

acceptance tests

manuals

procedures & governance for safe use

There should also be technical management and support available for the AI system. Besides that, the AI system should be *integrated into another architecture* or an existing platform or application for daily use. It should also have a *kill switch* if things go wrong. Besides that, there should be technical management and support available.

functional management & support

AI system integrated into architecture

kill switch

To uphold accountability the *governance and agreements* made with third parties and other stakeholders are in place for when the AI system is in production. A *risk management plan* should be in place and a new *DPIA* should be

technical management &support

done for when the AI system is in production. A *post-market clinical follow-up plan* has to be in place, just like a *post-market surveillance plan*. A definitive version of the privacy statement and terms and conditions should be in place, and of course: the AI system should officially be *released*, including its *privacy statement and terms and conditions*.

released AI system

Finally, there should be defined *limits of use* of the AI system in its context. To prevent other mistakes, *unforeseen consequences* must be considered and the *responsibility* of each stakeholder should be clear if any come up. *Bias* in the AI system should be addressed if undesired and should be communicated with the end user.

limits of use

consideration of unforeseen consequences

desired bias

Use

During the last phase continuously there is checked whether the AI system still *adds value*. By using continuous monitoring of the added value and impact, there can be checked if the added value is still larger than the risks or other negative effects. Besides that, there should be continuously monitored if there are any *functionality changes* for the end user, and in case of any changes, if there is a change in added value. Also, the impact for each stakeholder should be monitored to *identify positive and negative consequences.* Next to that, a plan should be made for *scaling up* and the *business case* should already be adapted to that.

For in the future, *lessons learned* during the development of this AI system have to be identified and noted for future studies and versions. Not only should there be a continuous monitoring cycle but also a continuous *test and evaluation cycle*. Whenever the AI system is updated there should be created new *manuals and pieces of training*. Whenever the architecture where the AI system is integrated changes, a plan should be made for integrating the AI system into this *newer architecture*. Also, there should be a technical plan for *scaling up* the AI system, including different *manuals and documentation* about the AI system.

lessons learned

Whenever the post AI system is also used externally, *post-market surveillance* has to be carried out in which there have to be reported incidents and any major technical changes. Besides that risk and quality management processes have to be implemented for continuous monitoring of the AI system and its *user experience*. In case of any changes to the AI system, a new *DPIA* has to be carried out. Besides that, the *risk classification* for information security has to be reassessed periodically.

At last, the *trust* in the AI system has to be monitored by both the user and the patient. Besides that, the *effect on care relationship* should be measured to prevent and identify any bias. *Undesired bias* should be identified and prevented to provide equal care to all patients. Also, there should be evaluated if there are any *limitations exceeded* to not overdo things. Finally, *future difficulties* should be monitored.

Scale up/down

This is a continuous process in which the different monitoring processes developed in the previous phase are running and checking whether the AI system is still viable.

4.4 Deliverable List

To get further insight into the different deliverables, an overview is created of all the described deliverables, this overview can be found in Appendix B. For each deliverable, further background is provided to get a better grip on what the deliverable is and how this deliverable can be achieved. Both white and grey literature is used to describe the different deliverables, as not all concepts from literature could be publicly accessed or would fully circumscribe the concept. The deliverable diagram describes the following aspects of each deliverable:

- Phase
- Domain
- Deliverable name
- Reference

Not all deliverables have an attached reference as some of the deliverables do not need a larger background as they are dependent on context-specific requirements or are standard checks for the AI system.

To prepare the deliverable diagram for modelling, the deliverables diagram is extended with descriptions of the content of the deliverables to prepare them for conversion to the concept diagram in (Table B).

4.5 Chapter Summary

This chapter described the five different domains in which the different deliverables mentioned in the Innovation Funnel for Valuable AI take place. These

deliverables are elaborated at the hand of the seven different phases in which they occur. The different deliverables are mapped in the delivery diagram, in which they are linked to literature to get a better background understanding of what the deliverables are and how these can be created.

Chapter 5

Applying AI systems in Healthcare in an ethical manner

To be able to describe different ethical dilemmas within the innovation of AI systems within healthcare the Dutch Digital Government has described multiple recommendations within the Toolmap for Responsible AI [112]. These recommendations can, and will, act as a starting point for the implementation of an AI system for this study. The Dutch Digital Government describes seven different guidance points 5.2:

- Centralize public values
- Involve stakeholders
- Respect laws and other obligations
- Beware software security
- Release bias from data, algorithms, and analyses
- Be transparent and accountable
- Monitor, evaluate and adapt

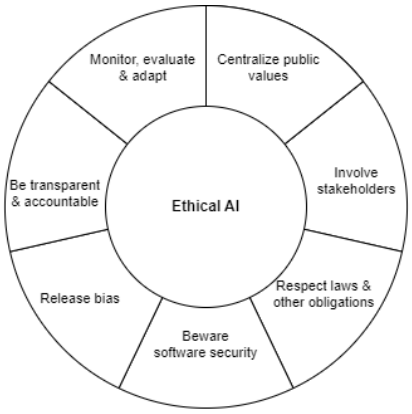


Figure 5.2: Seven guidelines by the Dutch Digital Government [112]

Each of the different guidelines has its own set of instructions which improves the main guideline. In the following chapter, each guideline will be further elaborated at the hand of their main focus point and their corresponding instructions (figure 5.3). To be able to apply these rules in practice, this model is extended at the hand of corresponding literature which applies to the rule in the correct context. This extended model is further elaborated in chapter 5.8.

Figure 5.3: Subdivision of the guidelines by the Dutch Digital Government [112]

5.1 Centralize public values

Every person, country, or culture has its values. However, values can be seen as a vague concept. To properly go into dept, a proper understanding of this term has to be used to solidify the understanding and discussion. Schwartz [123] describes values as the following:

> Values are concepts or beliefs, pertain to desirable end states or behaviors, transcend specific situations, guide selection or evaluation of behavior and events, and are ordered by relative importance.

Different from attitudes, values are more abstract but can more easily be put by a person within a hierarchy.

Displaying the effects of the AI system on public values allows for a better judgment of public values. This increases the transparency of the AI system and can increase the quality of the AI and thus the care provided. These values not only have to be known but also have to be taken into account during the entire development and testing process. At the hand of different methods, like brainstorms or ethical reflections, public values and their impact on them can be opened for discussion.

5.1.1 Awareness of difference in values

Working with a large group with the same goals will aid the AI system in becoming more effective and reliable, as these people work towards a set standard. It can be hard to set the same goals within a team as people have different values. So setting the same public values within a team is vital. However, it is hard to change people their values, However, creating awareness of the different values which exist, helps to improve the conversation. Schwartz [123] originally proposed ten different universal values, observed across the world. Later, these values were updated into nineteen values around twenty years later[125]. These values try to reflect the different values of people all over the world. As the guidelines portray, people must be aware of the different values of people.

5.1.2 Map effects of innovation on public values

Innovations such as AI systems can have an impact on many people. To properly address this, the values which the AI system under development impacts must be mapped. By mapping the impacted values, their effects can be taken into consideration and allow for a responsible integration of an AI system. To map these values, different methods are in place such as the Artificial Intelligence Impact Assessment [151] or the ethics assessment framework for research and innovation [48].

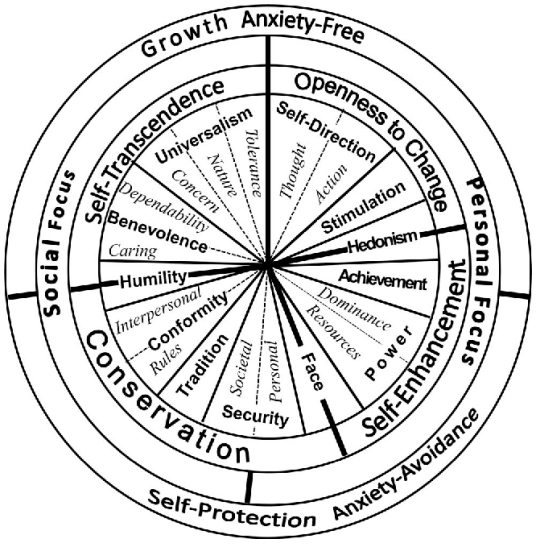


Figure 5.4: circular model of different values [125]

5.1.3 Take public values into the development process

Taking these different values into the development process can be done at the hand of multiple ways. Concepts like privacy by design [49] allow for the development of a non-intrusive design. However, a non-intrusive design can still lead to irresponsible decisions within an AI system. That is why in each phase of the development process, there should be assessed whether the system goes beyond the values it stands for. As a quick reminder, three main principles are defined by the IEEE for the development process[110]:

- Embody the highest ideals of human beneficence as a superset of Human Rights.
- Prioritize benefits to humanity and the natural environment from the use of A/IS.
- Mitigate risks and negative impacts, including misuse (..)

5.1.4 Allow dilemmas of values to be discussable

Values differ between people, Schwartz proved in the pre-updated version of his values that a sinusoidal relation existed between the values and between sexes [124]. Not only do people have differences in values but when developing an AI system, there is already a current status quo in place. This can be an existing organization, application, or existing organized audience. These already have values in place which also have to be taken into account. A three-way division can be made for the different values [139], at the hand of which, the public values can be mapped for the AI system under development. Driving values are

the values that aim for the innovation of the new AI system and are often the driving factors for a group of people to begin with an innovation. Embedded principles are the principles held by the current status quo and can act as a counterweight to the driving values. These values are often already in place and also can act as protection towards clients and other people using the AI system. Finally, process values allow for structured consideration between the driving values and the embedded factors.

5.2 Involve stakeholders

Involving the stakeholders ensures no misunderstandings are made about responsibility. Especially with external software providers, a contract must be created for who picks up responsibility whenever a defect occurs. Besides that, not only do have all stakeholder responsibilities, but they also have interests in being involved in the AI systems development which has to be mapped, for instance, at the hand of a checklist. Whenever a conflict of interest occurs between stakeholders or the development team and a stakeholder. There must be made sure that the dialogue has to be started as soon as possible to prevent escalation.

5.2.1 Be aware of other interests

As mentioned in previous paragraphs, different stakeholders have different values. These values lead to different interests regarding the use and outcome of the AI system. By allowing the dialogue between involved parties and the development team, these values can become clear during the development process. To manage the different interests of each party the SHARED principles can be used [63]. These principles aim to allow the perspective of other parties to be taken into account and allow for better engagement. Besides that, physical locations can be set up to involve stakeholders in the experiments. Also, a collaborative research agenda can be set up to allow for transparency in the experiment and allow stakeholders to create meetings and events.

5.2.2 Start the dialogue early

The first principle of the SHARED principles is the sustainability of the engagement with other stakeholders. Starting early with introducing these stakeholders allows for the sustainable development of an AI system. Having a dialogue with stakeholders can be done at the hand of multiple methods such as interviews and holding group discussions. Also, an online platform can be created to allow for a digital dialogue at the hand of social media, creating polls or other online applications.

5.3 Respect laws and other obligations

In the medical field, there is a substantial amount of laws and guidelines which have to be adhered to. Because it is such a sensitive field, there should be paid sufficient attention to who is responsible for every aspect of the AI system. Cutting corners can result in major consequences. Not only will the trust in the AI system plummet, but it might also affect the quality of care provided. In early phases, there should already be made clear which laws apply in later phases of the development process.

5.3.1 Respect the Constitution and general human rights and values

Whenever an AI system is implemented, it can have great effects on a person's life. This is especially the case in the healthcare industry where decisions are made about a person's health. That is why many guidelines and laws are in place to uphold the quality of AI systems. Not only has an AI system uphold quality standards but it has to uphold all national and international laws such as, but not limited to, the constitution[1], International Covenant on Civil and Political Rights[20], Convention for the Protection of Human Rights and Fundamental Freedoms[21], General Administrative Law Act[23], and the Archives Act[22].

5.3.2 Work within the legal frameworks for data use

An AI system's success often is made by the quality and amount of data it can use. As the pitfalls framework (chapter 3.4) already described, having a limited amount of data or unprepared data can make an AI system less functional. However, it is not ethically responsible to just retrieve as much data as possible. Only data may be gathered which is deemed necessary. That is why in the Netherlands, private information is secured via the General Data Protection Regulation (AVG)[140]. To measure the safety of private information a Privacy Impact Assesment (PIA) [131] and the Data Protection Impact Assesment [5].

AVG/GDPR

Sometimes, organizations are not able to fully be transparent about how their systems work as this can reduce their advantage in the market or when the system is used for public security. It is up to the owner of the AI system to show they comply with the different privacy rules imposed by the government in the

[1] https://www.denederlandsegrondwet.nl

Algemene Wet Gegevensbescherming (AVG) [4]. In Europe, these regulations are provided in the General Data Protection Regulation (GDPR) and are the same as the directives recorded in the AVG [30]. The AVG describes six different basic principles which have to be adhered to [3]:

- lawfulness, propriety and transparency;
- purpose limitation;
- data minimisation;
- accuracy;
- storage limitation;
- confidentiality and integrity.

5.3.3 Determine relevant laws and regulations in early stages

At the beginning of a new project, the legal framework must be well thought out to prevent any miscommunications or issues in the mids of the process which results in the project having to stop. The different laws and regulations described in the previous paragraph are all good practices to keep in mind when doing ethical research. Another important part in the Netherlands is that whenever a pilot is implemented in Healthcare, it has to apply to the Central Review of Medical Research Involving Human Subjects Decree [27] at the METC or CCMO.

METC/CCMO

One of the more important aspects on a practical level for research is that in the Netherlands, to be allowed to do research in the medical field, the study has to pass a review by the Medical Ethical Testing Commission (METC). Dependent on the type of research, the study has to be reviewed by either the Central Commission of Human Research (CCMO) or by a certified METC. This is dependent on the type of research, defined in the Central Review of Medical Research Involving Human Subjects Decree [27]. This law makes it necessary for studies, such as cell therapy, making vaccines, or doing research on pregnant people, the study has to apply to extra requirements and go through the acceptance process of the CCMO instead of solely the METC.

5.4 Beware software security

Patient data is highly sensitive. There should be aimed to depersonalize all data used. This will prevent a leak of patient data whenever a data breach occurs. Also, data anonymization can prevent data bias as it will solely rely on objective data. To ensure the risk is as small as possible, data and software security should be part of the total process. Besides that, spreading awareness and giving training about software security can improve the security itself.

5.4.1 Make information security part of the process

Vulnerabilities in software can have terrible consequences. Especially with personal data can a data breach be detrimental. Implementing different security procedures, like reducing access to the software or writing access by certain users, can reduce the risk of data loss. To incorporate the security of the systems and its data from early on different methods can be used. For instance, using the Security-by-Design principle which aims for incorporating security measures from early design phases [50]. Also, the Baseline for information security by the Government (BIO)[7] allows different product owners to create measures for software security.

5.4.2 Make people aware of risks

Making people aware of the different risks in software security helps mitigate risks in software and data security. An AI system´s users need proper training and documentation about the use of the system to aid in this mitigation, including these stakeholders early in the process can help people familiarize themselves with the system to avoid crucial mistakes. Just like in paragraph 5.2.2, early inclusion is a vital part of the process to create software ethically.

5.5 Release bias from data, algorithms, and analyses

In the systematic literature review, there could already be seen that bias in data selection is hard to prevent. However, there should be aimed to provide the system with unbiased, correct data so it can provide the best care possible. This can be done by aiming to reduce the workload of the data-gathering process so no corners are cut or solely already present data is used. By having the system ask the correct questions bias can be prevented, and including domain experts in the development process can aid in this. Bias in the final output can be prevented by selecting the correct type of output. The output has to be interpreted by the user if this output is not in an easily interpretable, or incorrect way. The result can be biased or wrong. Besides that, the literature review showed also, that a data shift can increase algorithm bias as it is trained on outdated data. So there should not solely be correct data present, but this data should also be kept up to date.

5.5.1 Get good data

As already discovered in the pitfalls framework (chapter 3.4), having proper data available is a key feature of a proper AI system. A lack, of outdated or non-suitable data, can lead to a less accurate AI system. To guarantee proper data quality, different steps can be taken [138]. By defining the quality of own and external data, apart from its context, an objective view of the data can be made, also the quality of the data sources has to be defined and maintained. This knowledge about the quality has to be made explicit before further steps can be taken.

5.5.2 Ask the right questions

One of the hardest parts of using an AI system is to measure whether its algorithm asks the right questions at the hand of the training it has had and the data presented. Not having the algorithm ask the correct questions and analyze the correct data, wrong decisions can be made or bias can be introduced. Whenever this occurs, there has to be deducted where such mistakes originate from. At the hand of decision trees [87], there can be visualized how these decisions are made.

5.5.3 Determine your output in advance

Determining the type of output in advance can assist in the validation of it in later phases. Having a predetermined type of output can leave as little

to interpretation as possible. This aids in creating an objective view of the resulting output.

5.5.4 Choose the right analysis method

To properly assess whether the correct method is used during the training of the algorithm, proper analysis has to take place. The analysis method used has to apply to different factors and has to be able to undergo analysis by others [138]. To be able to properly analyze the analysis method applied, it should apply three different rules; It should be transparent about which method is used and how this method is applied to the current situation. There should be a public consideration of interests and transparent training and testing of the AI system.

5.6 Be transparent and accountable

Transparent AI systems allow for a higher willingness of healthcare experts to adopt an AI system. Being transparent about an AI system does not only mean preventing the AI system from becoming a black box but also knowing its limitations. These limitations can aid in the future of the AI system by improving them. Besides that, it allows healthcare workers to provide better care as they know why certain decisions by the AI system have been made. This increases the feeling of responsibility by the healthcare experts as it becomes harder to point toward the system whenever an unwanted decision is made. As the limitations are known by the healthcare workers, they are provided with knowledge of when to overrule the system. To be able to be fully transparent, efficient communication is necessary. At the hand of the ART principles: Accountability, Responsibility, and Autonomy (figure 5.5), an accountable and trustworthy AI system can be developed [60].

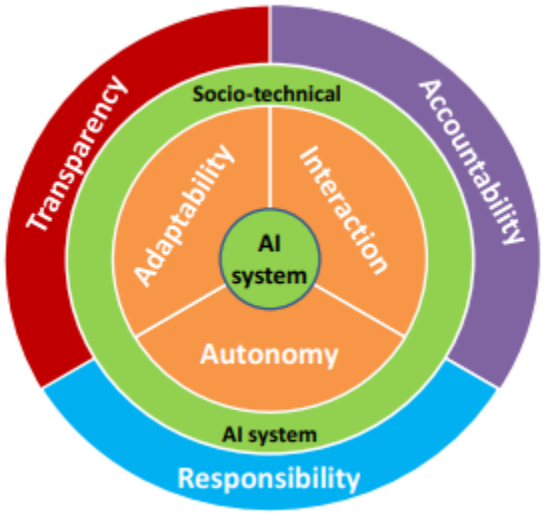


Figure 5.5: The ART principles: Accountability, Responsibility, Autonomy [60]

A toolkit that also describes this is the Ethical Data Assistant [6].

Having efficient decision-making methods within a team can strengthen the decision-making processes. One such system is the RADAR model [28]. The RADAR model stands for: Recognize, Assess, Decide, Act, and Review. It aims for effective ethics management by creating situational awareness at the hand of these six steps.

5.6.1 When designing, aim to be transparent

As previously mentioned, being transparent about the analysis method used, aids in the ethical value of the AI system. However, this does not solely apply to the analysis method. The entire design process should be transparent. As also was described in chapter 3.3, one of the main pitfalls of the implementation in AI systems is its transparency. One of the ways to the Dutch government forces its bodies to be transparent, is at the hand of the algorithm register [113]. At the hand of this register, each organization within the government has to register what algorithms they use, for what purpose, and what data they use.

5.6.2 Be accountable

Being transparent is different than the full public access to a system and being accountable. Being accountable for an AI system is deciding whether the decisions made for the design are derivable and explainable by the decision-making process used.

5.6.3 Ensure effective communication

Being transparent is not enough when this transparency can not be found by the stakeholders. Effective communication is a vital part of being transparent. An initiative by the government is the Coordinated Vulnerability Disclosure (CDV) [51]. This guideline aims for efficient communication between owners of ICT products. The aim of these communications is to allow for the early discovery of faults in systems and thus increase the safety of their products. Another manner this can be done is at the previously described algorithm register[113]. Also, involving stakeholders during the entire process allows for this transparency and constant communication with the stakeholders.

5.7 Monitor, evaluate, and adapt

Continuous monitoring allows for constant measurement of the efficiency of the AI system. To prevent any unwanted bias, a data shift, or a lack of added value. this process is vital. To be able to properly monitor in later phases, monitoring should already be part of the development process. The system should also be able to adapt to different findings from the monitoring. This also helps keep the system flexible, thus creating a continuous improvement cycle in the final phase of development.

5.7.1 Make monitoring part of the development process

Monitoring aids the development process as it helps to get a better understanding of the processes and current deliverables within a process. This understanding helps the development team to mistakes within the process and keep an eye on critical points such as data security or usability. Doing frequent assessment and classification such as, for instance, the risk classification [142] or the DPIA [5] can aid in keeping a grip on these critical points within the development of an AI system. Monitoring can be divided into three different types [34]: result-oriented monitoring and evaluation, Constructivist monitoring and evaluation, and reflexive monitoring and evaluation.

5.7.2 Build in correction possibilities

Automatizing can be a fantastic feature of any system. However, when a mistake is made in the development of the application or the training of the algorithm, it can lead to dire consequences. To properly allow the AI system to adapt to mistakes made, it should be feasible for the system to adapt and detect when correction is necessary.

5.7.3 Evaluation is not the final point

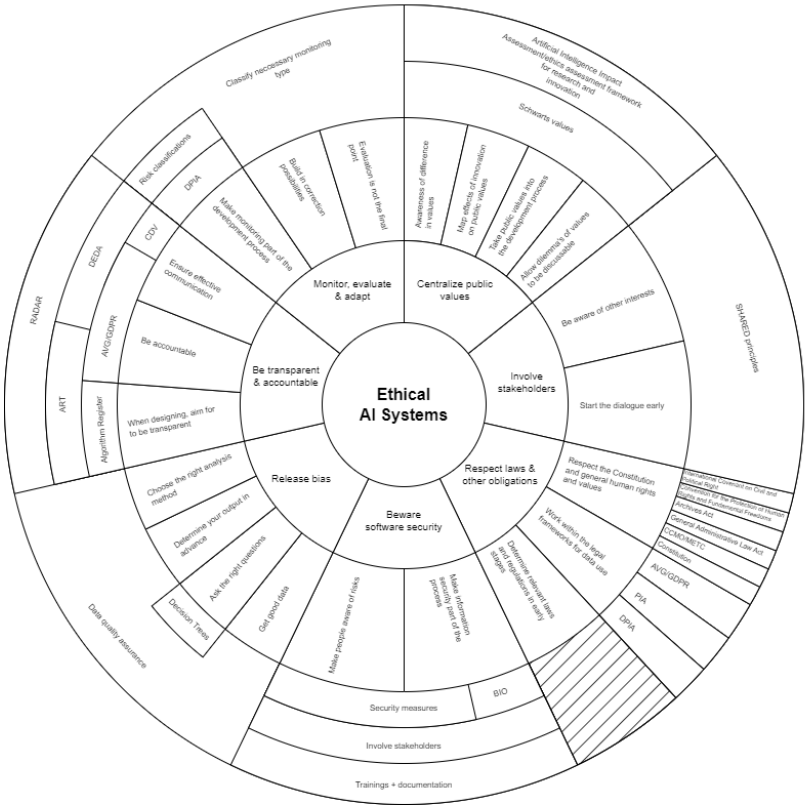
Constant monitoring of an AI system allows for these correction possibilities to be properly used. Monitoring different aspects of an AI system allows it to stay relevant and prevents different issues from occurring.

5.8 Extended Toolmap

The Toolmap for Responsible AI displays the different fundamentals for implementing an AI system in an ethical manner. As can be deducted from the previous paragraphs, there are already many articles written about the different key points of the Toolmap. These different methods and attention points described in the literature are applied to the Toolmap for Responsible AI in figure 5.6. Each of the seven guidelines is extended with the different key points or methods previously described. Some of these key points or methods apply to the whole guideline, while others only apply to a single instruction within the guideline. There has been aimed to portray the different guidelines as equal to not having any guidelines or key points portrayed as more important.

The main goal is to have the Extended Toolmap as a means of guidance to a party wanting to implement an AI system in healthcare in an ethical manner.

Figure 5.6: Extended version of the Toolmap



The following methods and attention points have been described, in the final column a reference can be found where the method/attention point is

introduced for further context:

Table 5.1: Added methods and attention points to the extended toolmap

Guideline	**Method/Attention point**	**Paragraph**
Centralize public values	Schwartz values	5.1.1
	Artificial Impact Assessment	5.1.2
Involve stakeholders	SHARED principles	5.2.2
Respect laws & obligations	International Covenant on Civil and Political Right	5.3.1
	Convention for the Protection of Human Rights and Fundamental Freedoms	5.3.1
	Archives Act	5.3.1
	General Administrative Law Act	5.3.1
	CCMO/METC	5.3.3
	Constitution	5.3.1
	AVG/GDPR	**??**
	PIA	5.3.2
	DPIA	5.3.2
Beware software security	Security measures	5.4.1
	BIO	5.4.1
	Involve stakeholders	5.4.2
	Tranings & documentation for security	5.4.2
Release bias	Decision trees	5.5.2
	Data quality assurance	5.5.4
Be transparent & accountable	Algorithm register	5.6.1
	AVG/GDPR	5.6.1
	CDV	5.6.3
	Artificial Impact Assesment	5.6.3
	DEDA	5.6
	RADAR	5.6
Monitor, evaluate, and adapt	Risk classification	5.7.1
	DPIA	5.7.1
	Monitoring type	5.7.1

5.9 Chapter Summary

In this chapter, the different guidelines provided by the Dutch Digital Government in the Toolmap for Responsible AI have been elaborated on and have been extended. At the hand of the different methods described for the different instruction aimed at the different guidelines, there is aimed to be able to allow for ethical implementation of an AI system. These methods have been visualized in a chart which displays the relationships between the different guidelines, instructions, and methods.

Chapter 6

Method Engineering

This chapter will provide more insight into how methods are created, and different approaches to method engineering to get a better insight into the basics of method engineering and choose a suitable method to design the method for application in the use case.

To go properly in-depth into the different methodologies and to be able to compare them, a proper understanding of the concepts used in the method engineering field has to be made clear to determine the current context. Brinkkemper proposes standardized terms for method engineering [43]:

Method A method is an approach to performing a systems development project, based on a specific way of thinking, consisting of directions and rules, structured in a systematic way in development activities with corresponding development products.

Activity A technique is a procedure, possibly with a prescribed notation, to perform a development activity.

Tool A tool is a possibly automated means to support a part of a development process.

Methodology The methodology of information systems development is the systematic description, explanation, and evaluation of all aspects of methodical information systems development

6.1 The Concept of Method Engineering

Method engineering is an engineering discipline that can be used for designing, constructing, and adapting methods, techniques, and tools for the development of information systems [43]. However, the concept is not limited to this description as it may include all aspects of the design process of a method. The

concept was first introduced as methodology engineering by Kumar & Welke [79] who invented the terminology as a solution for creating methods in information system development methodologies (ISDMs) but later more commonly accepted as method engineering (ME). Method engineering has many different types of subcategories such as situational method engineering, incremental method engineering

6.1.1 Situational method engineering

Situational method engineering (SME) is the practice of method engineering in which existing methods are used and adapted to the current context [117]. Kumar & Welke [79] already coined the term situational method engineering in 1992. The situation-specific method, as they call it, has to fit the situation, be complete, and each component has to be proven to work separately from the other. A situational method is often derived from other, already existing methods. This can be partly a new method, partly existing, but also a complete adaptation of already existing method fragments. Harmsen et al. [68] show how a situational method develops over time at the hand of the ISDM life cycle (figure 6.2):

1. In different projects, generic activities are identified and saved as approaches
2. These approaches codified form together different methods
3. From these published methods, situational methods are derived and published as part of new methods

6.2 Meta Modelling

To be able to compare different methods a dedicated approach has to be chosen. One of the approaches which can be used is meta-modelling [80], in this approach a model is made of the conceptual framework of the modelling language. A meta-model is the abstraction of a model, or the occurrence where modelling has taken place twice [78]. The process of abstraction can be compared with the process of generalization of an event. In this process, irrelevant details are removed from this event, such as temporary details or attributes belonging to an object [65]. This allows for a comparison of the semantics and syntax of different models.

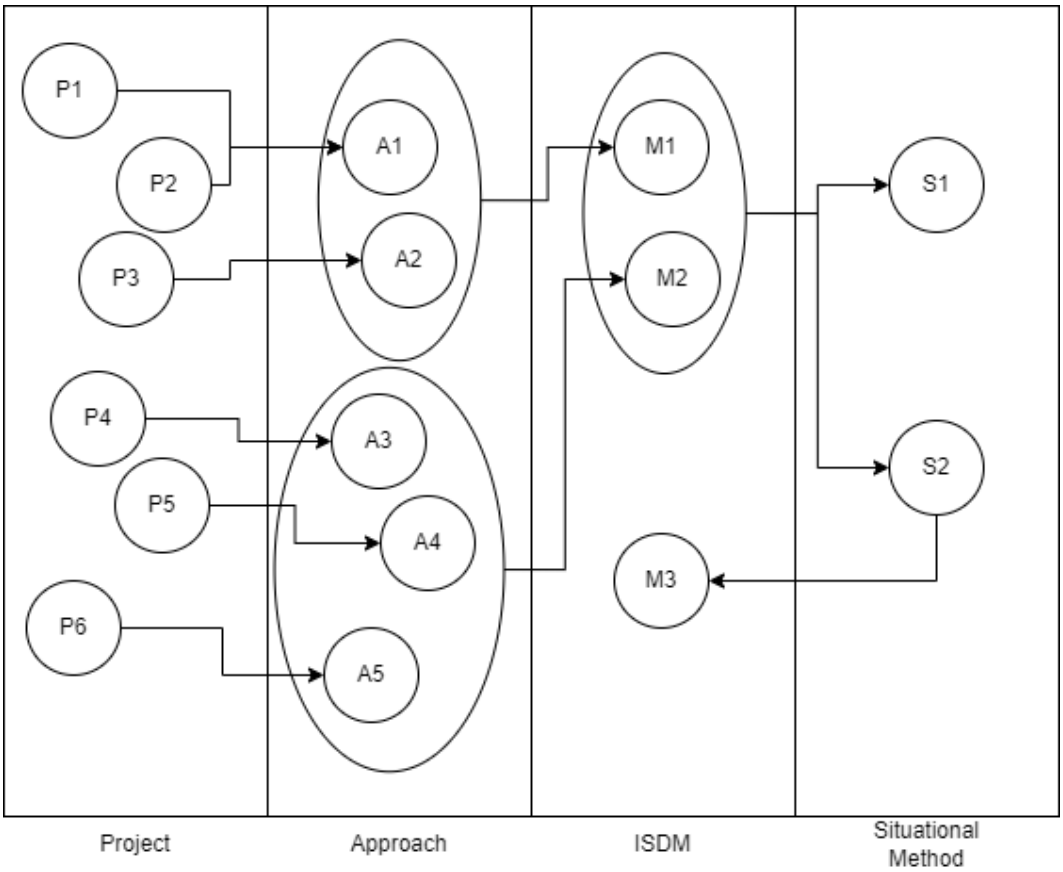


Figure 6.2: Recreation of the ISDM life cycle by Harmsen et al. [68]

6.2.1 example

A good way to understand this abstraction of model and data is the four-layer approach [115]. In this approach, the real world and its abstractions are divided into four different levels of abstraction, with each level being an abstract representation of the level above it. At the hand of these different levels, it is possible to identify different models at the hand of their abstraction level and use their abstraction for a better understanding of the model

M0: Data level	The representation of the real world
M1: Model level	An abstraction of the real world data / data level
M2: Metamodel level	An abstraction of the model used in M1,
M3: Meta-metamodel level	An abstraction of the abstract model generated in M2

To get a further understanding of this abstraction, an example is given at the hand of a use case. The M3: Meta-metamodel level is taken out of this scope due to the simplicity of the example given.

In a school there three different courses are given; Languages, Mathematics, and Gymnastics. These classes are given by a single teacher to a group of at least one student. These courses are given in different classrooms, but can sometimes be followed from a live stream from a different classroom. These classrooms are provided by the school, which also creates the room schedule for the lessons to take place. An M0: data level of this use case can, for instance, be the schedule of a student (table 6.2.1)

Table 6.1: Student schedule example

Schedule 23/02/23				St nr 789654213
Time	**Room**	**Online**	**Course**	**Teacher**
09:00	1.03	no	Gymnasistics	John Smith
12:00	2.01	yes	Mathematics	Jane Smith
14:00	1.12	no	Languages	Brandon Fraser

This student schedule is on the M0: Data level, it shows a possible real-life scenario for a student. However, if the school has a large number of students, too much data can obscure the overview. To convert this schedule to the M1: Model level, an abstraction has to be made. In this case, an abstraction of the data is already present in the table. The time, room, course, and teacher are all already abstractions of the data which is present in the table. Online can be seen as a characteristic of the course. That leaves the student, with a student number, and the schedule itself as the final objects (figure 6.3. These objects have relations, first, the schedule itself is presented as an object. It has a relation to both the student and the course object. The relation is as follows; a student has always a single schedule (1.1), however, a schedule always needs a student to exist. but can exist for each student present (1..*). Student and course also have a relation as students follow courses, a course can only be given if there are one or more students (1..*) but students can follow 0 zero courses (if they no longer need to follow the provided courses this period) (0..*). Courses are given by a teacher, each teacher at least one course in a single subject. However a teacher can give multiple courses (1..*), and a course is always given by a single teacher (1..1). Students can follow courses both online and in person, thus the characteristic online is a boolean for the course. Courses are given in one to multiple classrooms, as lectures can be followed online and in person, thus a one-to-many relationship (1..*). A classroom can remain empty, or host multiple classes over the day (0..*).

To create a further abstract of this model, there can be four different objects seen at the M2: Meta-model level; Concepts, relations, characteristics,

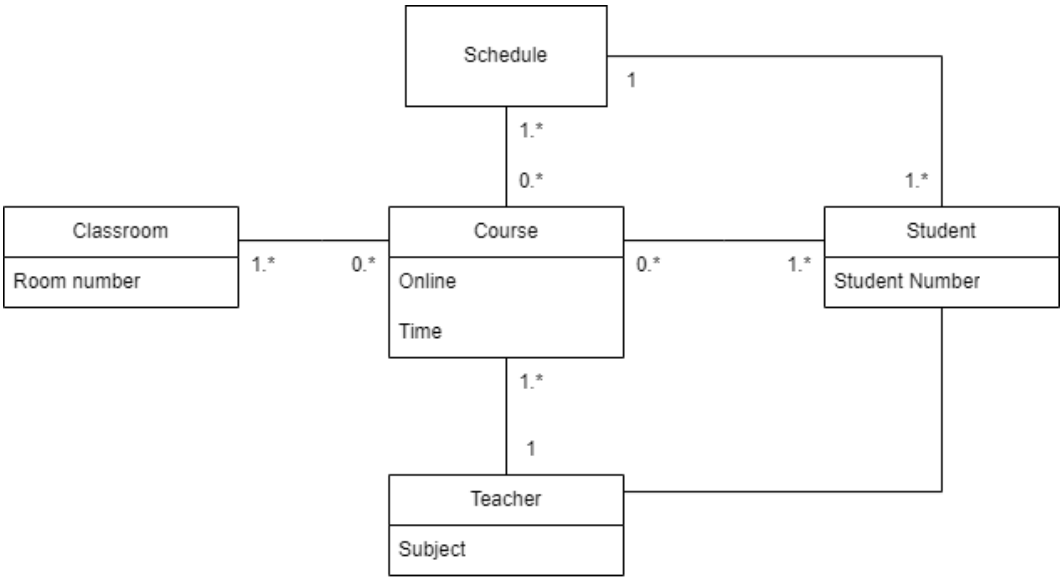


Figure 6.3: Example of a model of a student schedule

and multiplicity (figure 6.4. The different concepts such as the classroom, schedule, courses, etc. at the M1 level are connected at the hand of relations. Each concept has at least one relation (1..*) but each relation should always link two concepts (2). To define the number of concepts needed within each relation, a relation always has two multiplicities (2) as on both connection points from the relation to the concept, the number of necessary concepts must be known. Finally, the different concepts can have characteristics to further define their traits in further detail (0..*), a characteristic is always part of a concept (1).

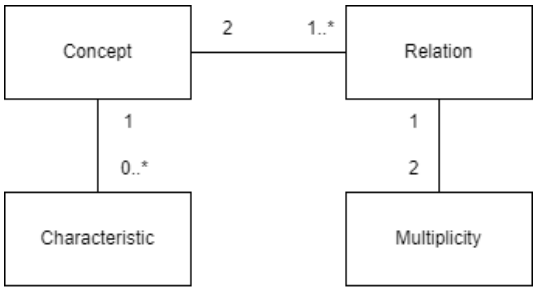


Figure 6.4: Example of a meta-model of a student schedule

6.2.2 Metamodelling as a proven method

Meta modelling is a widely used method for design evaluation [126]. To properly understand the model the UMCU uses, meta modelling would be a suitable

approach to get a better grip on this method. One of the methods to use meta modelling as an assessment strategy is using the Process Deliverable Diagram (PDD) [144].

6.3 Process Delivery Diagrams

The PDD aims to visualize the meta-model and give a clear view of who the stakeholders and actors are during the different activities. Besides that, it gives a clear view of the different concepts used which are products of the different activities. For a clear overview of both, the PDD is supplied with an activity table and a concept table. The activity table provides an overview of each activity and a short description of it. The concept table provides each concept and a description of said concept, usually with corresponding literature. Whenever a concept is used during an activity.

In the next section, the syntax and semantics of the PDD will be further elaborated. A visual representation of the different syntax and semantics can be found in figure 6.5.

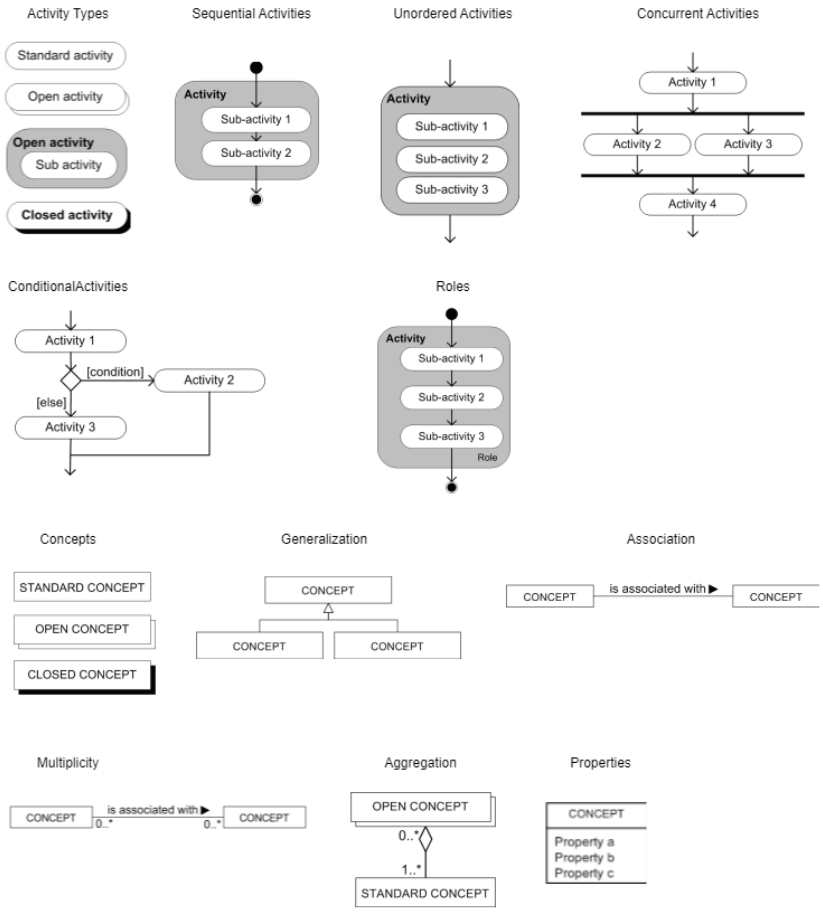


Figure 6.5: PDD syntax and semantics by van de Weerd & Brinkkemper [144]

Activities

A PDD consists of activities, these activities describe different tasks or efforts which have to be made by different actors within a single process. Activities can be divided into two different characteristics:

Standard activity An activity without sub-activities

Complex activity An activity with one or multiple sub-activities. There are two different complex activities:

Open activities are complex activities of which the sub-activities are known and portrayed in the PDD. This can be done at the hand of two different methods. Or all sub-activities are placed in the same box or the activity has a white shadow.

Closed activities are complex activities of which the sub-activities are unknown or not relevant to the current context of the PDD. Instead of a white shadow, they are displayed with a black shadow in the PDD.

Activities in PDDs can, just like in the real world, occur in different orders. As some activities deliver concepts, the order can be of uttermost importance. However, in some occasions, activities occur side by side, or it does not matter at all in which order different activities occur. The PDD recognizes three different orders in which activities can occur:

Sequential activities are activities that occur in a pre-set order. The activities are portrayed vertically from each other and connected with arrows in the order they occur.

Unordered activities are in no apparent sequence. They can occur side by side but the order does not matter. Unordered activities are usually part of a complex activity. They are portrayed as loose activities without a sequential arrow, instead of that, above and below the unordered set of activities a horizontal line is present at which the sequential arrow connects from the previous and to the next activity.

Concurrent activities happen side by side at the same time. Different from unordered activities, which can happen at any time in any order, these activities have to happen at the same time. They are portrayed in the PDD similarly to the unordered activities. Above and below the activities a horizontal line is displayed connected with a sequential arrow to the previous/next activity. Instead of the unconnected activities, the horizontal dividers are connected to multiple sequential activities within the horizontal dividers and connected by arrows to the horizontal dividers.

Not all activities are mandatory in a process, this can be the case as sometimes extra validation is necessary or activities only have to occur in specific situations. A **condition activity** is portrayed by a diamond shape from which two sequential arrows originate. These arrows have so-called guard expressions which show the condition, the condition is shown between square brackets. It always has a single outgoing arrow with the condition and an outgoing arrow with the [else] statement.

Roles

In some processes, it must be known who is responsible for certain activities. Roles can be notated with the position within the organization of the responsible person in the lower right corner of an activity. If within a complex activity, a single person is responsible for all sub-activities, the role can be defined in the lower right corner of the complex activity and does not have to be redefined for each sub-activity.

Concepts

Concepts can be seen as the deliverable side of the PDD. These concepts originate from different activities. Just like activities, there are two different types of concepts:

Standard concept is defined by a rectangle, it has no other concepts in it.

Complex concept are concepts that have aggregations with other concepts. Two different complex concepts are recognized:

An **Open complex concept** is a concept that has expanded sub-concepts. It is visualized with a white shadow. Its aggregations can be shown in the same PDD, or a different one, often dependent on the complexity.

An **Closed complex concept** is an aggregated concept of which the aggregations are unknown, or out of context for the current PDD. It is visualized with a black shadow.

Concepts know different relations. These relations show the connections between the concepts, like if they are part of each other or if there is any municipality.

Generalization This relation shows the relation between a concept and one or multiple more specific concepts which can be seen as the same. It is visualized by a solid arrow with an open head coming from the specific concepts and pointing towards the generalized concept.

Association An association shows how two different concepts are related to each other. This usually occurs whenever more context is needed on how these two concepts relate to each other. It is shown as a small black arrow and text on how to relate above the relational arrow.

Properties Some concepts have more information assigned to them. These are depicted in lowercase in a square below the concept.

Multiplicity This feature describes how different amounts of concepts are related to each other. This can be a binary relation but also a one-to-many or none-to-many. It is defined by the amount, for example, 0..* (a 0 to many relation) at the receiving end of the relational arrow.

Aggregation An aggregation is a special type of association. It can describe a 'has-a' or a 'consist of' situation.

In chapter 7, this method will be used to visualize the UMCU method for the implementation of an AI system.

6.3.1 Example PDD

An example PDD is provided at the hand of the different steps to get a better understanding of how these different concepts work together to create a PDD. As can be seen in figure 6.6, the PDD describes the different activities described at the method design. There are two larger complex activities with smaller complex activities, Problem Investigation and Treatment Design, which describe the main research phases. The activities, described in table 6.3.1, result in different concepts, described in table 6.3.1, which are part of two larger open complex concepts. First the method design, first, and second RQ are described which form together the long proposal. This long proposal is graded and presented. After the long proposal is presented, the third and fourth RQ are described and validated. Together with the contents of the long proposal, the thesis draft is created. Feedback from the supervisor is given and the draft thesis is finalized into the final thesis, which is presented at the thesis defence.

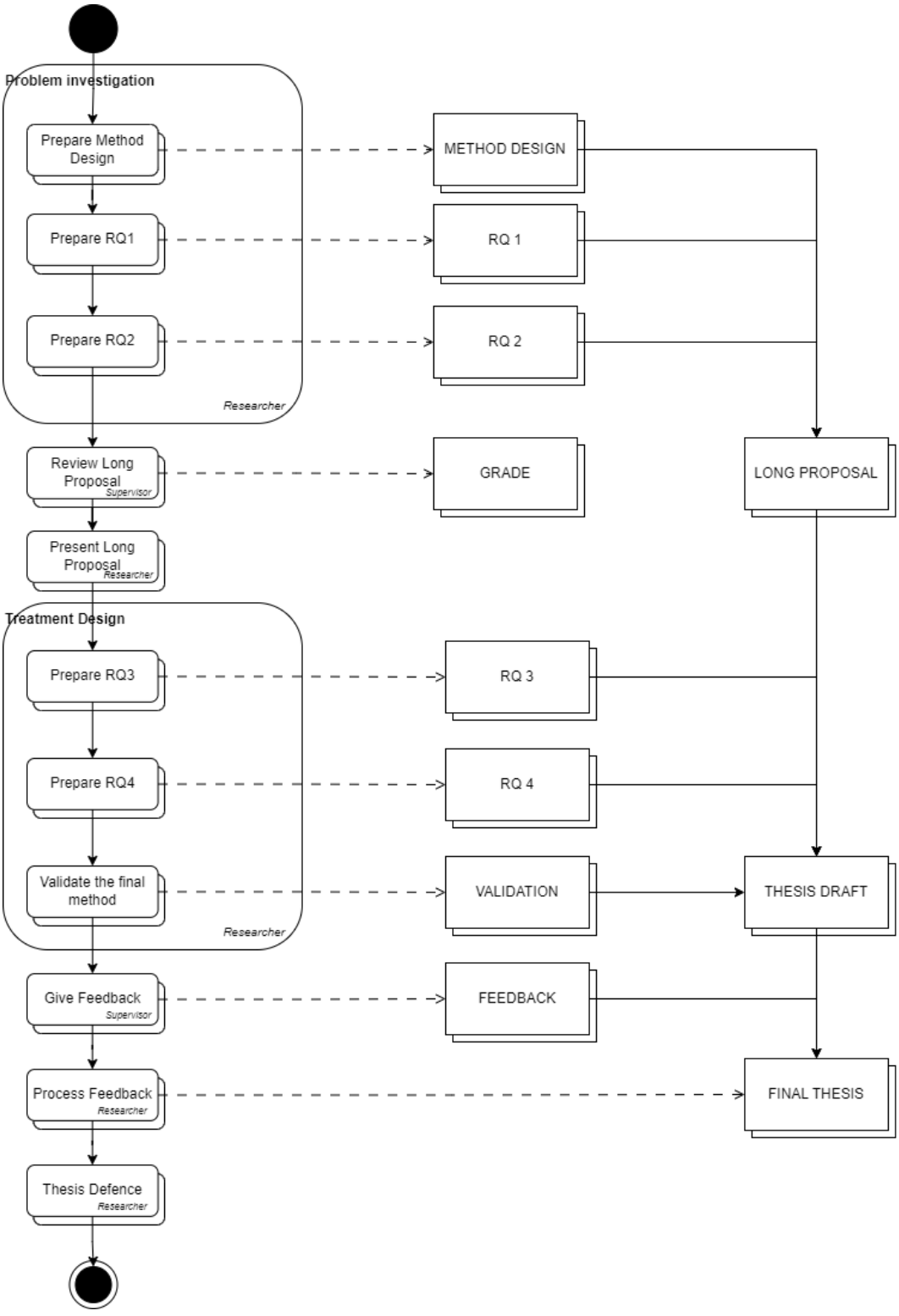


Figure 6.6: Example PDD of the different steps taken during the thesis

Table 6.2: Example Activity Table of the Thesis process

Activity	**Sub-activity**	**Description**
Problem investigation	Prepare Method Design	The METHOD DESIGN is created by the researcher, selecting the different RESEARCH QUESTIONS and choosing the RESEARCH METHODS
	Prepare RQ1	A study to answer RQ1
	Prepare RQ2	A study to answer RQ2
Review Long Proposal		The supervisor gives a GRADE for the LONG PROPOSAL
Present Long Proposal		The researcher presents the LONG PROPOSAL to its peers and receives FEEDBACK from the group
Treatment Design	Prepare RQ3	A study to answer RQ3
	Prepare RQ4	A study to answer RQ4
	Validate Final Method	A VALIDATION is created for for the created method in RQ4
Give Feedback		The supervisor gives feedback about the DRAFT PAPER
Process Feedback		The FEEDBACK is incorporated into the FINAL THESIS and delivered
Thesis Defence		The final presentation is held

Table 6.3: Example Concept Table of the Thesis process

Concept	**Description**
RESEARCH METHOD	The method used to answer the RESEARCH QUESTIONS
RESEARCH QUESTION	Questions which describe the problem aimed to be answered in a question form
METHOD DESIGN	An overview of how different RESEARCH QUESTIONS are answered at the hand of the different RESEARCH METHODS
RQ1	The first RESEARCH QUESTION
RQ2	The second RESEARCH QUESTION
LONG PROPOSAL	A document consisting of the RESEARCH METHOD and RESEARCH QUESTIONS describing the literature study
GRADE	A numerical value which describes the value of a test or deliverable
RQ3	The third RESEARCH QUESTION
RQ4	The final RESEARCH QUESTION
VALIDATION	A test to see if the implementation created with the RESEARCH QUESTIONS works
DRAFT PAPER	A document which acts as a placeholder to receive FEEDBACK on
FEEDBACK	Additions and remarks given by peers and the supervisor at the hand of the DRAFT PAPER and received during the presentation
FINAL THESIS	The final deliverable, an improved version of the DRAFT PAPER using the provided FEEDBACK

6.4 Chapter Summary

This chapter describes the aim of method engineering and meta-modelling. The meta-modelling technique PDD is elaborated which puts activities and concepts side by side, allowing for the integration of the many deliverables elaborated in the deliverable list. Also, an example of using PDDs is given at the hand of the structure of this study.

Chapter 7

Process Documentation

To visualize the processes of implementing AI systems within the UMCU, different methods are used to promote the understandability of the processes. First, PDDs are created on different levels of scope in the process to describe the different complexities within the process and deliverables. The first PDD created describes the process on a similar scope as the Zenya dashboard. On this scope, the overall process can be documented and the main deliverables can be made clear. Secondly, the PDD will be extended by other PDDs to narrow down the scope and increase the amount of detail. These PDDs have the open concepts from the initial PDD as their final deliverable and aim to combine the final deliverables within the PDD at the largest scope. Besides portraying the method in different PDDs. A dashboard is created to allow users who are less familiar with method engineering documentation to get a better grip on the complex method.

7.1 Process Delivery Diagrams UMCU

As elaborated in chapter 4, the Innovation Funnel for Valuable AI in Healthcare has seven phases, each separated by a gate which acts as a go/no go moment. Each phase has its own project report in which most deliverables can be checked off. The deliverables with the highest priority are included in this PDD.

Each phase is included in its own open activity. The activities within describe the creation and processing of the different deliverables needed to be able to pass the gate. These are visualised as the different concepts within the PDD, although usually a separate concept table is created per PDD. For this process, a sole concept table is introduced due to the large number of concepts which return and are updated within the process. How these different concepts are exactly updated can be found in the activity tables, which are displayed per phase.

7.1.1 PDD Zenya

On the highest level is the PDD of the processes and actions processed in Zenya (Appendix C.1). As is previously described, the Innovation funnel for valuable AI is divided into seven different phases, each phase has a go/no-go moment called a gate. The different phases in the PDD are displayed using an open complex activity, containing the activities to fulfil the different deliverables. Dependent on the phase, the activities within the open complex activities differ, however, each phase has a project report to conclude the different findings. Each gate is separated from the other with a conditionality which is dependent on the decision by Digital Health. The different deliverables within a phase are all part of the same project report as this is the main deliverable at the end of a phase. The project reports all aggregate in a chronological manner as the different activities within the project report activities use the concepts created.

7.1.2 Project Reports

In the project reports the different deliverables are prepared in the corresponding phase. Most of the activities preparing the different concepts are not time-dependent and can be done at the same time or in random order. Thus a large open complex concept is used to portray these activities in which the activities are unordered. Some activities are ordered however, this order is independent of the grand scheme of the open complex activity of preparing the project report, but are dependent on other activities. For instance, in the first phase, a determination is made whether the AI system acts as a medical device or as a regular system which aids the healthcare process. If there is determined that it is a medical device, a medical device class has to be assigned to the medical device, however, this is only possible whenever the activity 'determine medical device' has already occurred. These activities are portrayed within a separate open complex activity within the overall open complex activity.

The different concepts originate from the corresponding activities. Some concepts aggregate which each other as they are dependent on each. Some of the activities do not provide a concept, but they provide a property to a previously created concept. Concepts are often carried over from a previous phase. During the carrying-over activities, these concepts are often updated, for instance from a draft version to a more complete version, or additional concepts are added to the origin of concepts. However, to not have an overflow of aggregations within the PDD to keep its readability, there is chosen to use an update icon for the concepts updated, instead of the regular aggregation syntax. The concept with the previous project report is part of the PDD to display that its part of the process.

Almost all concepts are summarized in the final project report, thus the

many aggregations to the final project report which can be seen in the PDDs. These

In the next paragraph, one of the PDDs for one of the phases is highlighted and further elaborated upon

7.1.3 In-depth case elaboration

At the hand of the PDD of the Pilot A phase, a broader elaboration of the process is given to give an outline of the processes within all phases without falling into repetition.

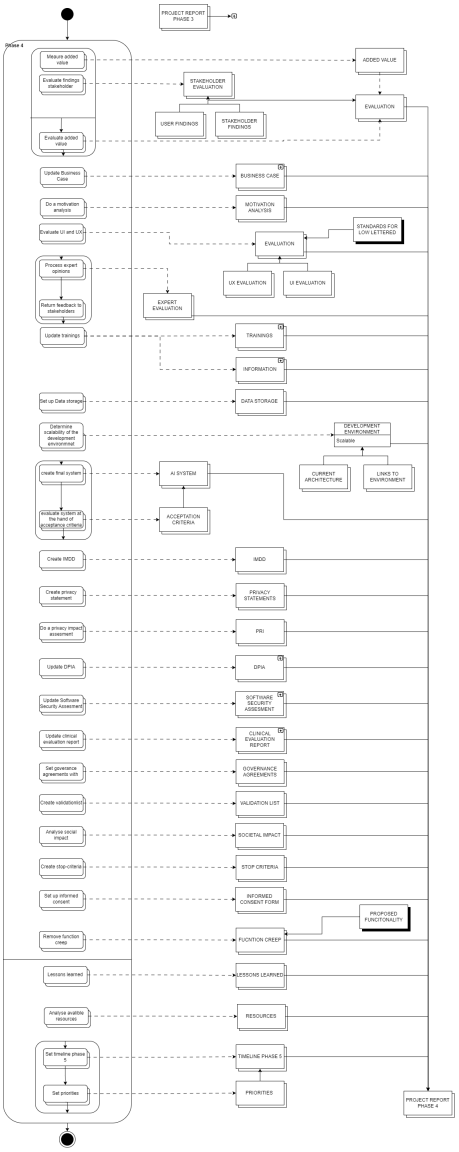


Figure 7.1: PDD Phase 4 - Pilot A

As described earlier, the phase is described in a single open complex activity called Phase 4. The PDD starts with a start activity, kicking off the large open complex activity. Besides this activity, is the stand-alone project report from the previous phase, aggregating to the update icon, identifying from which the other concepts with the update icon aggregate. The first activity described in the project report is the different deliverables for the evaluation of the non-clinical pilot. To do this evaluation, the added value has the measured and the findings of the different stakeholders have to be evaluated. Both these activities do not have to happen in this order but can occur in any order. However, they both have to be finished before the added value can be evaluated. The stakeholder evaluation is divided into two different concepts as the user of the AI system often has different findings than other stakeholders. The different findings are part of the same general concept.

During this phase, there are multiple activities which update a previously created concept, such as the DPIA, trainings, and business case. These are marked with the update icon to show that they make changes to the already in phase 3 created DPIA, trainings, and business case.

At the end of the phase, different activities have to be done to finish the activity and prepare for the next activity. At the hand of the pilot, different lessons learned have to be documented and planning and its priorities have to be noted. These activities can only be done as if all previous activities have been finished. Besides that, all concepts aggregate to the final project report concept, which summarizes the activities done during this phase and acts as a way for Digital Health to control the process.

In the next part, all aggregations and concurrencies are elaborated for each phase. The activities which solely lead to a single concept and have no concurrency are left out of this elaboration as they are already elaborated in the phase description in chapter 4.3.2

PDD Idea phase

As the idea phase is the first phase in the Innovation Funnel for Valuable AI, no previous project report is present as a concept from which previously prepared concepts can be aggregated. A problem description is described at the hand of the SCQA method, which all aggregates to the problem description concept. Next to that, the different stakeholders are identified, which differ from regular stakeholders in the precise determination of the end user of the AI system. The determined value is predicted at the hand of the added value for patients, healthcare providers, and the overall organization. Besides that, an estimate is made of the number of patients affected by the AI system. The strategy is analysed at the hand of the current analysis at the UMCU. The technique used for the AI system is determined and a check is done if it will be made in-house, or made by an external party. Besides that, there is checked if there is currently already a comparable product which can be bought or used (for instance, open-source software). A determination is made whether the AI system can be perceived as a medical device and has to apply to the MDR. Different contracts have to be made with external parties and with the UMCU to start the implementation. When all other activities are finished, there has to be a check of what resources are necessary and available to be able to conduct the next phase. Besides that, a timeline has to be created for the activities in phase 2. Priorities have to be set for these priorities.

PDD Exploration phase

The second phase starts with the previous project phase, it starts with an aggregation to the update symbol, which specifies which concepts are updated from the previous project report. The problem description is updated at the hand of the SCQA method, with the situation, complication, questions, and answers aggregated to the problem description. At the hand of a stakeholder analysis, which determines the final users, stakeholders, and the pros and cons per stakeholder, user stories are created. A competitor analysis is done, which aids in the market scan. Also, an investor has to be found, which will make funds available. These available funds are added to the business case, which is updated from the previous project report. A set of acceptance criteria for the final algorithm has to be created, which results in the algorithm properties to which the algorithm has to adhere to. There has to be determined whether the final AI system counts as a medical device, and has to be classified at the hand

of the MDR criteria. Also, a production company has to be chosen to produce the final AI system, a rating has to be done on whether this organization applies to the MDR/IVR qualities and contracts have to be made. When all activities are finished, the available and necessary resources have to be analysed to run the next pilot phase. Next to that, a timeline for the next phase has to be created, after which the priorities of the activities have to be set. The PDD ends in an aggregation of all concepts to the project report.,

PDD Development phase

First, the previous project report is integrated as a concept with aggregation to the update icon, to indicate which concepts are updates from the previous phase. The development phase also starts with the problem description, elaborated and aggregated to the situation, complication, question, and answer. Stakeholder feedback has to be retrieved to determine, which consists of expert input and user input. At the hand of this, the design requirements are set up, the AI system is tested at the the hand of the design criteria, consisting of the UX and UI design criteria and the corporate identity of the UMCU. Also, a final version of the medical device determination has to be done, with the incorporated MDR/IVR class, set as its properties. Also, there has to be determined whether a CE marking is needed, which is also incorporated as a property. The device has to receive a risk class. A plan has to be created to run pilot A, which gets an aggregation of the definition of the product type activity. This activity results in the pilot setting, in which the pilot will take place. At the end of the phase, when all activities are finished, lessons learned have to be noted, there has to be analysed whether enough resources are available and what resources are needed, and a timeline has to be created for the pilot A phase, including the priority of the activity. The phase ends with the aggregation of all concepts to the project report phase 3 concept.

PDD Pilot A phase

First, a concept with the project report of the previous phase is present with aggregation from the project report phase 3 concept to the update icon. The added value of the pilot has to be measured, including an evaluation of the stakeholders. They come together in a final evaluation of the added value. Also, the UI and UX have to be evaluated at the hand of the standards for low-lettered people. An expert opinion evaluation has to be done and this feedback has to be returned to the different stakeholders in the process. The development environment and its scalability have to be determined. This concept and its property get an aggregation from the links to the development environment and the current architecture. Making the overview of the development environment complete. The final AI system is also created during

this phase, which, after its creation, has to be evaluated at the hand of the acceptance criteria. When all activities are finished, the lessons learned during this phase have to be noted, available and necessary resources have to be documented for the next phase to work, and a timeline has to be set up, including the priorities of the different activities within the timeline. The phase ends with the different concepts created for the project report phase 4 concept, which summarizes it.

PDD Pilot B phase

The pilot B phase begins with the concept of the project report of the pilot A phase, which aggregates to the update icon which indicates the update of the concepts. An evaluation of the UX and UI is done which both aggregate to an UX and UI concept. Also feedback is retrieved from the users and other stakeholders. Which also both aggregate to the feedback. When all activities are finished, a timeline has to be created for the next phase, and priorities have to be set for the different activities within this phase. The phase ends with a concept of the project report phase 5 to which all finished concept aggregate.

PDD Implementation phase

This phase starts with the concept of the previous project report, it aggregates to the update icon. During this phase, a description of the usefulness and necessity is created. This description consists of a usefulness description and a necessity description which both aggregate the overall description. The governance and support have to be checked and updated with external suppliers. When all activities are done, the available and necessary resources have to be checked and a timeline has to be created for the final phase. The phase ends with a concept of the project report phase 6 in which all finished concepts aggregate to.

PDD Use phase

The last phase is introduced with the concept of the previous project report, which aggregates to the update icon. The rest of the phase consists of loose activities, mainly setting up different kinds of monitoring types. Their concepts aggregate to the final project report phase 7.

7.1.4 Concept Diagram

The start of the concept diagram (table B) has been converted to a final version of the concept table (table C.9). At the start of this research, there was assumed that the different deliverables elaborated in the Innovation Funnel for

Valuable AI would one on one present within the project reports. However, when modelling, it came to the attention that a large number of these deliverables were not present, or did not have the same names. Thus a conversion was done with the correct concepts to properly portray the concept originating from the different activities.

7.2 Toolmap v.s. Innovation funnel

Seven different guidance points are described in the Toolmap for AI innovations [112]. These guidance points are divided into multiple actions which should be taken to allow for the ethical implementation of an AI system. The Innovation funnel for valuable healthcare [100] acts as a guideline for the implementation of AI systems at the UMCU. To check whether the Innovation funnel for valuable AI suits the ethical guidelines the activities will be cross-referenced with the activities mentioned in the Toolmap for AI innovations. In table 7.1 the proposed activities from the Toolmap for AI innovations are presented with the corresponding activities taken in the Innovation funnel for valuable AI. There is both looked at the activities mentioned in the slide deck and the activities derived from the project reports.

Table 7.1: Crossreference of the ethical guidelines compared to the Innovation Funnel for Valuable AI and Project reports

Toolmap subject	**Toolmap guideline**	**Deliverable**	**Activity**
Centralize public values	Awareness of difference in values	begeleidingsethiek	check medical values, measure scientific added value
	Map effects of innovation on public values	User Stories,	Create user stories
	Take public values into the development process	Verification of norms and values	check medical values, measure scientific added value
	Allow dilemma's of values to be discussable	Unforeseen consequences considered	consider unforeseen consequences
Involve stakeholders	Be aware of other interests	impact on equalities	analyse social impact

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Toolmap subject	Toolmap guideline	Deliverable	Activity
	Start the dialogue early	begeleidingsethiek	
Respect laws & other obligations	Respect the Constitution and general human rights and values	Investigational Medical Device Dossier (IMDD), DPIA	create IMDD, CCMO control, determine if CE marking
	Work within the legal frameworks for data use	DPIA, Information security risk classification, information security risk classification, risk classification	create IMDD, CCMO control, determine if CE marking
	Determine relevant laws and regulations in early stages	process exploration, Investigational Medical Device Dossier (IMDD), DPIA, contractual arrangements	create IMDD, CCMO control, determine if CE marking
Beware software security	Make information security part of the process	DPIA, Information security risk classification, information security risk classification, risk classification	update software security assessment, update clinical security assessment
	Make people aware of risks	Limits of use, clear responsibilities for correct use, end users are trained	finish training, finish manuals, actualize risk management plan, install quality and risk management processes
Release bias	Get good data	Data Storage available through data standards, data end report	Analyze Data Availability, Determine Technique, create data management plan
	Ask the right questions		create algorithm validation report
	Determine your output in advance	data end report	Determine Technique, create data management plan

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Toolmap subject	**Toolmap guideline**	**Deliverable**	**Activity**
	Choose the right analysis method	Validation plan, Incentive analysis	Determine Technique, create validation list, create algorithm validation report
Be transparent & accountable	When designing, aim to be transparent	Limits of use, Desired Bias	Make AI transparent
	Be accountable	strategic ambassador, Clear responsibilities for correct use	create stop criteria
	Ensure effective communication		
Monitor, evaluate & adapt	Make monitoring part of the development process	Measuring and monitoring system in place, Monitoring for expected added value, Monitoring for changed functionality, Monitoring for positive and negative consequences, Monitoring for positive and negative, Monitoring level of trust consequences, Monitoring effect on the care relationship, Continous monitoring of possible future difficulties	Implement measuring & monitoring system
	Build in correction possibilities	function creep removed	remove function creep, check functionality

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Toolmap subject	**Toolmap guideline**	**Deliverable**	**Activity**
	Evaluation is not the final point	Measuring and monitoring system in place, Monitoring for expected added value, Monitoring for changed functionality, Monitoring for positive and negative consequences, Monitoring for positive and negative, Monitoring level of trust consequences, Monitoring effect on the care relationship, Continous monitoring of possible future difficulties, post-market surveillance plan	Implement measuring & monitoring system, set up a transfer to managers, install monitoring

From the table can be derived that most of the instructions from the Toolmap for AI Innovations can be derived from the deliverables mentioned in the Innovation Funnel for Valuable AI and the Zenya project reports. For the guidelines 'centralize public values', 'respect laws & other obligations', and 'monitor, evaluate & adapt', activities and deliverables could be found for all instructions. For most of the instructions, multiple deliverables and activities could be found that applied to the instructions, applying even better to the ethical value of these guidelines. However, for three different instructions, no deliverable or activity could be derived:

- Start the dialogue early
- Ask the right questions
- Ensure effective communication

'Start the dialogue early' is described in the Innovation Funnel for Valuable AI as part of the Begeleidingsethiek. As can be read in chapter 5.2.2, this

instruction aims to involve different stakeholders early in the process to allow for better inclusion of the people who regularly only would be getting into touch with the process in later phases.

'Ask the right questions' is not part of the Innovation Funnel for Valuable AI but is part of the Project Report as part of the algorithm validation report. As can be read in chapter 5.5.2, asking the right questions, aims to describe the correct questions the AI system should ask to properly come to conclusions when processing data. This validation is a vital part of the AI system's algorithm as it deduces whether it works properly. More background information could be added to the Innovation Funnel for Valuable AI about the validation of the AI system's algorithm to fully comply with this ethical instruction.

'Ensure effective communication' is the only instruction which could not be derived from either the Innovation Funnel for Valuable AI, or the Zenya process reports. As can be read in chapter 5.6.3,

7.3 Dashboard

To further aid in the visualization of the different deliverables and processes within the implementation of a new AI method at the UMCU, a dashboard has been created.

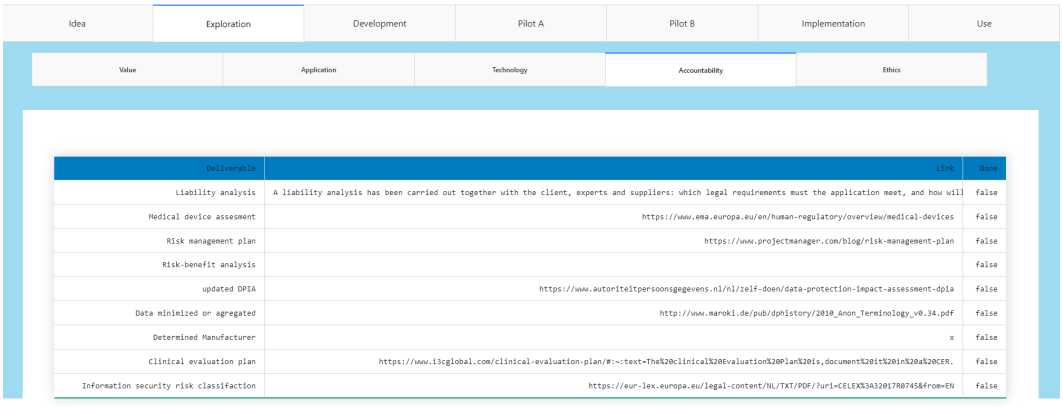

Figure 7.2: The created dashboard

7.3.1 Language and framework

The dashboard has been created using Python Dash [1]. The programming language has many open-source libraries which can be used for data analysis and

[1] https://plotly.com/dash/

portraying large data sets. Python Dash is an open-source framework using the Python programming language which can be used to create dashboards and display data. Besides that, by using Python, it can easily be used as an extension on the original C2R software which is also partly written in Python.

7.3.2 Data preparation

At the hand of two set of tabs displaying each phase from the 7 phases model [100] and each domain per phase. The concept table with the different variables is imported as a comma-separated value (CSV) file and converted into a dataframe. This dataframe will act as the basis for the dashboard.

7.3.3 Dashboard functionality

Python dash works with callbacks whenever an action takes place on the page. It uses different inputs and outputs which can be assigned by the user. This system uses the different tabs as the input to create a subset of the dataset. Depending on the phase and domain tab selected, the corresponding deliverables are selected and displayed in a datatable beneath these tabs. A datatable has been chosen over a regular table as it allows for interactivity, as a regular table is just a visual representation of a dataframe.

Whenever the user clicks on the 'Done' cell of the corresponding deliverable, the value changes from false to true for the deliverable in the dataframe. As the visualized table is a subset of the dataframe and not the total dataframe itself. Thus, a query is used to find the clicked value in the original dataframe. This query uses the selected row, to find the name of the deliverable, and the tabs previously mentioned. At the hand of these three values, a unique selection can be made for the total dataframe (as there are recurring deliverables within the framework).

7.4 Chapter Summary

This method describes the different PDDs created at the hand of the different methods used by the UMCU at the hand of an in-depth case elaboration and describes the outliers of the other phases. Besides that, the different activities and deliverables described by the UMCU have been cross-referenced with the analysis of the ethical implementation of AI systems. It is finalized by a dashboard which has been created to give more insight into the different deliverables and their background.

Chapter 8

Validation

This chapter describes the outcomes of the expert opinion interviews held at the UMCU. At the hand of these interviews, different changes have been made to the PDDs. First, there is described which people were interviewed, followed by the different outcomes of the interviews.

8.1 Expert opinion

At the hand of an expert opinion validation, the models have been validated. Two interviews have been held with experts on the processes of the Innovation Funnel for Valuable AI within the UMCU.

Three different semi-structured interviews have been held. In table 8.1

Table 8.1: Function and experience of the interviewees

Function	**Years of Experience**	**Years of Experience in ICT**
Data Scientist	3	11
Staff Advisor Digital Healthcare	1	2

During the interviews, the following four questions were asked, at the hand of which, an unstructured conversation followed:

- How does the Innovation Funnel for Valuable AI relate to the project reports on Zenya?
- Is there a set order in which the activities take place during a single phase?
- Do all activities have the same priorities, or does this differ per deliverable?

- How does Digital Health use the different activities described in the project report, is it a checklist or more a piece of guidelines?

8.1.1 Progression at UMCU

Currently, Digital Health is working on a newer version of the Innovation Funnel for Valuable to apply to the different guidelines for assessing an MDR. At the hand of the guide to quality AI in healthcare[148], they want to improve the current methods in place. This allows the UMCU to implement medical devices without extra validation from external sources. Currently, the Innovation funnel and project report do not suit the requirement needed for this. By improving the processes at the UMCU, they can streamline the process of implementing AI systems at the hospital. They are currently doing this by creating a quality report, in which different quality requirements are set, and different processes for how these requirements can be met. This quality report is also set up to improve the guidance within the processes of the Innovation Funnel for Valuable AI. This does not solely improve the understandability of the different deliverables, but introducing these processes also improves the guidance available by Digital Health for new ideas. This initiative is still a work in progress and started halfway when this study started.

8.1.2 Order within the Activities

During the initial method engineering, no real order of activities could be deducted from the Innovation Funnel for Valuable AI and the project report. From the outcomes of the expert opinion validation, this seemed to be currently the case. The different activities leading to the deliverables noted within the project report in a single phase can be done in random order. Except, for the concurrent activities which need information from previous deliverables.

It seemed that in previous implementations of AI systems, not all activities were finished during a phase. This could be caused by external parties, as validation by them could take longer, or that certain priorities were very low. These activities were still included in the next phase as all activities had to be finished and the project reports should be fully completed, otherwise, the documentation would not be complete. Although this happened, Digital health does not believe this is currently the common practice.

8.1.3 Activity Priorities

As there is no real concurrency within the different activities, there was tried to determine whether there was some flexible order within a phase. There is mentioned at the final stage of each project report that the activities in the

timeline for the next phase have to be prioritized, but no real prioritization is present within the project reports or the Innovation Funnel for Valuable AI. It seemed that activities got prioritized based on risk mitigation and how understandable they were. Activities which mitigate the risk of failure were often prioritized as they were seen as more important by the development team. Besides that, activities which were clearly described or had clear completion criteria were often prioritised. As for people not familiar with the different processes it is a safer choice to follow the steps of a well-elaborated activity than to identify the steps themselves during the activity.

8.1.4 Decision Moments

Besides the order of the different activities in a phase, the gate seemed to be a decision moment, rather than a go/nogo moment. The moment Digital Health decides whether the AI system is ready is the real measuring moment for the go/nogo moment. Not the moment all activities are finished or deliverables are ready. It seemed that some activities could be redone to update the deliverables and improve the chance of succession. This portrays a less linear view than is proposed in the Innovation Funnel for Valuable AI and the project reports. This also complies with the less linear view of the order within the activities.

8.2 Changes to models

As in previous instances different activities and deliverables have been transferred, there has been chosen to add this to the different phases to allow the instances where this happens. Although this is not common practice, it still occurred often enough to be notable by the personnel of Digital Health and thus should be modelled. At the end of phases 1 through 6, an activity was added that checks the completeness of the delivered activities and decided whether the activities will be updated in this phase, or will be brought with in the next phase. This also describes the iterative characteristic of a single phase as the activities. Although in the Zenya PDD, a recursive concurrency is present, this feedback is not present in the other PDDs. To all PDDs a feedback check activity is added, in which the completeness of the project report is checked, and if not complete, loops back to the start of the overall complex activity. To further tie together the different PDDs, there is chosen to add to the Zenya PDD an indication of the scope of the other PDDs to see in the blink of an eye what parts the other PDDs represent. At last, some mistakes and oversights were fixed to make the PDDs better fit to describe the Innovation Funnel for Valuable AI and the project reports and their deliverables.

The changes made to the previous PDDs are highlighted in the colour blue to indicate they were added in the second iteration.

8.2.1 List of changes

- Added missing deliverables concept to Zenya PDD
- Added iteration to phase PDDs
- Added missing deliverables to phase PDDs
- Fixed other mistakes in the first version
- Highlighted changes

8.3 Updated models

The previously described list of changes is applied to the PDDs, which can be found in Appendix D. The full change list can be found in table D.1.

Chapter 9

Conclusion and Discussion

9.1 Summary

This study aimed to discover and map the different processes within the UMCU to improve the implementation of AI systems within healthcare. This study originates from a C2R pilot currently running at the UMCU. Implementing AI systems in healthcare can lead to numerous pitfalls. Although there is a high willingness to work with AI systems within healthcare by healthcare providers, low user autonomy, non-transparent AI systems and not prepared or sufficient data, can lead to a less optimised AI system. At UMCU, they have the Innovation Funnel for Valuable AI for implementing AI systems. This funnel describes seven phases in which different deliverables have to be created to progress in the process of implementing an AI system. These different summarised at the hand of different project reports. These processes have been mapped at the hand of PDDs, a meta-modelling method which allows the mapping of different activities, in combination with their generated deliverables. Besides this, ethical research has been done to review how to implement an AI system in an ethical manner. This resulted in the extended toolmap in which different key points and methods have been mapped as guidance for implementing an AI in an ethical manner. At the hand of two different interviews with domain experts, the created models have been validated and adapted to improve their reliability.

9.2 Discussion

To answer the first research question, a SLR was held. At the hand of this SLR, there could be deduced that the main pitfalls took place in the willingness of adopting AI by healthcare providers, the transparency of the algorithm, and the readiness of the available data. Although there is often a high willingness to participate in pilots and working with AI systems, there is a high priority towards autonomous and understandable systems. Healthcare providers want to stay in charge of the decisions they make as they are domain experts and have more knowledge than others. This is also something which is the result of an autonomous, transparent AI system. Finally, the data used to prepare the AI system must be fit and there must be sufficient data to train and test the algorithm.

> Although the complexity of the number of deliverables and the methods, the method has been modelled using PDDs.

To answer the second research question, the different processes at the UMCU were mapped. During the creation of the deliverable list, a large number of deliverables came to the attention. Although a large number of deliverables are updated over the different phases and recur over the different phases, it does make the method very complex. It seems almost impossible for a small development team to keep an eye on all the different deliverables and have knowledge about all the different concepts introduced.

> When implementing the quality report at the UMCU, there should be aimed for alignment between the different documents and decreasing the complexity of the overall method.

This also became clear when answering the final research question. During the creation of the deliverable list, there was assumed the deliverables described in the Innovation Funnel for Valuable AI would directly fit the different concepts resulting from the activities in the PDDs. However, most deliverables described within the Innovation Funnel for Valuable AI do not align directly.

> The current deliverables described can be extended to improve the ethical state of the different phases. By focusing more on stakeholder involvement and describing the expected results of the algorithm at the start of the process.

For a future adaptation of the Innovation Funnel for Valuable AI and the project reports further alignment between the deliverables and the resulting concepts from the project reports is needed. This would improve the understandability of people who are not domain experts and allow for a smoother implementation of the AI systems within the UMCU.

> Decreasing the complexity of the different phases by removing, prioritizing, or combining different activities and deliverables.

Besides that, the UMCU should aim to decrease the number of necessary deliverables to increase understandability. For the implementation of a MDR, a great number of requirements are present, however, a distinction can be made in the process between the different types of AI systems implemented (For instance MDRs and non-MDRs). This could greatly decrease the number of deliverables and allow for a better understanding by the project team, especially when a lot of deliverables are not necessary for the development and implementation of the AI system.

9.3 Validation issues

9.3.1 Conclusion Validity

Unfortunately, only two interviews could be held with the experts from the UMCU. There was aimed to hold more interviews as this would improve the insight into the different processes and give more examples of real-life applications of the innovation funnel for valuable AI. Due to time constraints, experts being on holiday, and not receiving a response, only two interviews could be held in the end. Although, there was already noted during the second interview that a substantial number of findings were similar to the first interview. From this can be perceived that there already was some saturation. However, for full saturation, more interviews had to be held. As is described in chapter 2.3, to counter conclusion validity issues. Concrete and objective questions have to be asked during the interviews. This has been done at the hand of the different questions prepared during the set-up of the expert interviews.

9.3.2 Internal Validity

Internal validity guarantees the findings in this study were not found by chance. There has been aimed to mitigate this threat to validity by keeping a small scope; Dutch healthcare, and to be more precise: The UMCU. All processes studied were presented by the UMCU, at the hand of their processes and extra reading material, the literature was extended. It could be the case that papers, grey literature, or other reading material were overlooked. However, as these were not presented within their current methodology, these findings would not negate the validity of the described processes, but could only extend the created frameworks and toolmap.

9.3.3 Construct Validity

There has been aimed to keep the threat to the construct validity as little as possible by keeping the scope, just like the internal validity, as close as possible to the research subject. However, there is room for some improvement. The pitfalls framework could have been more extensive, by increasing the sample size of the SLR more pitfalls and takeaways could be found. Besides that, using a larger sample size could show different relations between the different pitfalls and strengthen the claims made. Also, having more interviews for the validation could strengthen the construct validity. It allows the outcomes of the study to be more rigid as real saturation would have been reached.

9.3.4 External Validity

As described in chapter 2.3, the external validity issues occur whenever the study is not generalizable. As this study has a small scope, the study should be generalizable within the UMCU. Within the Netherlands, different hospitals use different processes for the implementation of AI systems within their organization. However, all these hospitals have to adhere to the same laws and rules. As the UMCU has to adhere to the same laws as other hospitals, the methods created for it should be transferable.

9.4 Future research

This study has provided further background on the processes of implementing AI systems at the UMCU and how to implement an AI system in an ethical manner.

9.4.1 C2R pilot

This study can aid further the C2R, currently running a pilot. At the hand of a better background of the different deliverables in the Innovation Funnel and the processes at the UMCU, the process of the current pilot running can be smoothed. Besides that, it can also aid in the implementation of AI systems new at the UMCU, or implemented at other healthcare clinics. During the implementation of the current C2R pilot, the created methods can be updated according to the different findings over the phases.

9.4.2 New pilots

This research can be extended by implementing it in new scenarios. It will show whether the deliverables and their background are accurate and if it would smoothen the process by allowing the initiative party to have more insight into the processes and deliverables. There can be checked if, and how it would improve the process. It will also show the usability of the developed methods in a different context than the current context of the UMCU in which it is developed. Another potential study is to compare the method currently used by the UMCU with implementation methods at other hospitals. By comparing the different activities and deliverables, the necessary actions can be deduced to implement an AI system in healthcare and redundant activities and deliverables can be removed.

9.4.3 Improvement of UMCU processes

Currently, Digital Health is also improving the process including the innovation funnel and the project reports. The addition this study gives at the hand of extra background information and ethical guidelines that can help Digital Health improve its current processes. During the modelling, there was noticed that the deliverables in the Innovation Funnel for Valuable AI and the project reports do not match one on one. It would greatly improve the process to streamline these deliverables and make it easier to find the meaning of certain harder concepts. Also, the use phase feels a little out of place. Half the deliverables are constant monitoring processes, the other half are regular deliverables. It would be advisory to create a new monitoring phase with solely the monitoring deliverables, which kick in whenever a change occurs, or in regular intervals.

9.4.4 Continuation of digitalization

Continuing work on the digitalization of the methods and their deliverables could improve the interactivity between digital health and the implementation team. It would not only make it easy to look up the background of the different deliverables and track the methods needed to achieve them. But it also allows for a transparent process as both the implementation team and Digital health can follow the process in real-time. A dedicated implementation of the different necessities of implementing a pilot within healthcare, within the C2R software could also allow for an easier implementation of the C2R software in future instances.

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Appendix A

Pitfalls framework

Table A.1: Overview of the paraphrased findings and category

Reference	**Pitfall/Takeaway**	**Category**
[145]	The model should be generalizable	Generizability
	There should be paid sufficient attention to training and informing	Training & informing
	There is a need for explainable AI	Explainable AI
	When implementing AI you should involve end users early in the design process and perform pre-implementation	Preimplementation
[141]	There should be enough training data available	Data availability
	Attention should be paid to the limitations of the data used	Data limitations
	Attention should be paid to the limitations of the model used	Model limitations
[67]	Data retrieval should use as limited energy as possible for the patient	Workload data retrieval
	Questionnaires should not give a biased view	Selection Bias
	Using the AI system should have a limited workload	Workload AI system use
	Selection bias should be taken into account	Selection Bias
[46]	Informational disbalances should be prevented	Information disbalance
	In high stakes decision making the model should not be a black box	Explainable AI

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Reference	**Pitfall/Takeaway**	**Category**
	Administrative burdens should be prevented	Workload AI system use
	Prevent bias, the model should not discriminate minorities	Model Bias
	The interaction between human and AI should be easy	Human AI interaction
[146]	AI may result in an overflow of information, unmanageable for patients and physicians	Information disbalance
	Physicians were willing to use AI	AI Adoption Willingness
	The infrastructure of the system should be streamlined to the AI needs	System Architecture
	Patients familiar with AI are more willing to work with AI than people who don't	AI Adoption Willingness
	Acceptance of AI is driven by potential (dis)advantages	AI Adoption Willingness
[57]	Having a conservative approach with AI might have an underestimated the effect	Approach
	You should not solely rely on literature for input parameters	Reliability
	To measure effectiveness, AI should be used in all clinical phases	Effectiveness
	There was uncertainty regarding deployment and usage	Approach
[147]	The AI was applied at the wrong clinical stage	Approach
	Determine whether the subpopulation is the most appropriate population for adding value by an algorithm	Data availability
	The data underrepresented the number of cases	Data limitations
	The data was not detailed enough for some derivations	Data limitations
[56]	Standardization of nursing terminology would increase the AI feasibility	Data limitations
	Measuring added value can justify data collection	AI Adoption Willingness

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Reference	**Pitfall/Takeaway**	**Category**
	home healthcare providers involved in our study mainly provided care under a prospective payment system.	Selection Bias
	Only data was collected that district nurses found necessary to register for their clients.	Selection Bias
	Variations in how NANDA-I is applied by different districts influence the AI	Data limitations
[70]	Data transformation is extensive	Workload AI system use
	The administration of treatments and diagnoses is complicated causing inconsistencies among healthcare providers	Reliability
	The facilities to process and clean the numerous protected microdata sources are currently limited in the Netherlands.	Workload data retrieval
[42]	Limitations of the (available) data	Data limitations
	Reliability can be affected if data is retrieved in different intervals	Reliability
	The sample should be generalizable	Generizability
[58]	The data was not complete	Data availability
	Available data was not fit for analysis	Data limitations
[153]	Data-driven dimensional course outcomes caused a harder translation to clinical practice	Generizability
	Analyses were computationally demanding	Workload AI system use
	Missing data was filled with single imputation, while multiple would have been better	Reliability
	Generizalibility should be assessed independent from the overfitting of an AI system	Generizability
	Class-probabilities rather than memberships made the outcome harder to interpret,	Model limitations
	Model selection was driven by a single requirement, although not common practice	Reliability
	To allow inclusion, only baseline variables measured irrespective of diagnosis were included	Data limitations
	Final algorithm can be seen as a black box	Explainable AI

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Reference	Pitfall/Takeaway	Category
[36]	Most healthcare data is not ready for implementation in AI systems	AI Adoption Willingness
	A large barrier to AI systems is the lack of implementation	Approach
	Missing data affects model performance	Data availability
	AI systems can be used for missing data, preserving algorithm performance	Reliability
	The performance of an ML algorithm is only as reliable as the data used	Data limitations
	Data shift must be addressed	Data limitations
[37]	Data only contained a limited set of asynchronies.	Data limitations
	An invasive and non-standard procedure was used to obtain ground truth labels	Reliability
	The clinical dataset was more precise than the simulated dataset	Information disbalance
	Using a Neural Network Console causes the system not to be in real-time	Effectiveness
[133]	Integration takes a vital role for adoptation	AI Adoption Willingess
	Insufficient knowledge, trust, professional identity, and professional autonomy take a vital role in AI system acceptance	AI Adoption willingness
	The role of evidence on innovations plays a key role in adaptation	AI Adoption Willingness
	Job replacement can be a hurdle in the adaptation of an AI system	AI Adoption Willingness
[120]	Patients should be made familiar with the benefits of using AI systems	AI Adoption Willingness
	Accuracy and the risk of health inequalities should be addressed for AI systems	AI Adoption Willingness
	Efforts should be made on transparency, validation, accessibility for all skin types, and adequate regulation using AI systems	Approach
[129]	The Dutch government funds AI systems for healthcare, which citizens can use on their own responsibility	AI Adoption Willingness

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Reference	**Pitfall/Takeaway**	**Category**
[75]	In a qualitative study it is hard to generalize	Generizability
	Quantitative studies can provide a next step to uncover the extent to which patient decision support technology is perceived as desirable or undesirable.	Reliability
	AI systems should be advisory, not dictating	AI Adoption Willingness
	The current health experts working are key for acceptance of an AI system	AI Adoption Willingness
[62]	If the majority of people use a certain system, then other people are more willing to accept this system	AI Adoption Willingness
	The use of AI in the medical field can be a very sensitive topic	AI Adoption Willingness
	Trust in an AI system is critical for acceptance	AI Adoption willingness

Appendix B

Longtable Deliverables 7 phases

Table B.1: Overview of the different deliverables for the different phases with according to literature

Phase	**Domain**	**Deliverable**	**Ref**
Idea	Value	idea description	[101]
Idea	Value	tangible value at the hand of end user	[154]
Idea	Value	potential stakeholder list	[17]
Idea	Value	impact analysis	[151]
Idea	Value	Solution lifecycle	[164],[32]
Idea	Value	business case outline	[135]
Idea	Application	personas	[54]
Idea	Application	process exploration	[83]
Idea	Technology	data availability	x
Idea	Technology	impact analysis	[151]
Idea	Accountability	strategic ambassador	x
Idea	Accountability	feasibility & conditions for responsive use	x
Idea	Accountability	risk scan	x
Idea	Accountability	DPIA	[5]
Idea	Accountability	contractual arrangements	x
Idea	Ethics	broad impact analysis	[151]
Idea	Ethics	impact on inequalities	[151]
Idea	Ethics	analysis usefulness in medical practice	[40]
Idea	Ethics	begeleidingsethiek	[96]
Exploration	Value	Research question	[136]

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Phase	Domain	Deliverable	Ref
Exploration	Value	User stories	[52]
Exploration	Value	Stakeholder Analysis	[17]
Exploration	Value	Valorisation Strategy	[82]
Exploration	Value	Business case	[135]
Exploration	Value	Market Scan	[41]
Exploration	Application	client/patient journey	[39]
Exploration	Application	prototype solution	x
Exploration	Technology	Data end report	x
Exploration	Technology	Start Architecture	[18]
Exploration	Technology	Development plan	[119]
Exploration	Accountability	Liability analysis	x
Exploration	Accountability	Medical device assesment	[61]
Exploration	Accountability	Risk management plan	[122]
Exploration	Accountability	Risk-benefit analysis	[130]
Exploration	Accountability	updated DPIA	[5]
Exploration	Accountability	Data minimized or agregated	[114]
Exploration	Accountability	Determined Manufacturer	x
Exploration	Accountability	Clinical evaluation plan	[71]
Exploration	Accountability	Information security risk classifaction	[142]
Exploration	Ethics	Ethics by design	[104]
Exploration	Ethics	Proof of consent and autonomy	x
Exploration	Ethics	Required support for acceptable human interaction	[151]
Development	Value	Developed AI system	x
Development	Value	Demos of MVP	x
Development	Value	Refined Business Case	[135]
Development	Application	personas	[54]
Development	Application	Expert sessions with ambassadors	[160]
Development	Application	UX and UI requirements	[150]
Development	Application	Training	x
Development	Technology	Data collection, model and repository	[114]
Development	Technology	Architecture map	[18]
Development	Technology	Definitive algorithm	x
Development	Technology	Functional application/finished MVP	x

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Phase	Domain	Deliverable	Ref
Development	Technology	Definitive risk class	[142]
Development	Technology	certification plan	[11]
Development	Technology	updated Risk management plan	[122]
Development	Technology	updated Risk-benefit analysis	[130]
Development	Technology	updated DPIA	[5]
Development	Technology	Clinical evaluation report	[71]
Development	Technology	Information security risk classifaction	[142]
Development	Technology	Investigational Medical Device Dossier (IMDD)	[92]
Development	Ethics	Verification of norms and values	[148]
Development	Ethics	Application respects users autonomy	[60]
Development	Ethics	due diligence check	[13]
Pilot A	Value	Added value	[154]
Pilot A	Value	Demos of application	x
Pilot A	Value	available finanical resources	x
Pilot A	Value	Refined Business Case	[135]
Pilot A	Value	Validation Plan	[71]
Pilot A	Application	Incentive analysis	[55]
Pilot A	Application	Expert sessions with users	[160]
Pilot A	Application	UI evaluation	[106]
Pilot A	Application	Training and schooling	x
Pilot A	Technology	Data Storage	x
Pilot A	Technology	Scalable development environment	x
Pilot A	Technology	definitive application	x
Pilot A	Accountability	Governance and agreements with external suppliers	x
Pilot A	Accountability	Risk management plan	[122]
Pilot A	Accountability	updated DPIA	[5]
Pilot A	Accountability	clinical evaluation report with technical performance	[71]
Pilot A	Accountability	risk classification information security	[142]
Pilot A	Accountability	definitive IMDD	[92]
Pilot A	Accountability	WMO classification	[29]

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Phase	Domain	Deliverable	Ref
Pilot A	Accountability	definitive privacy statement	[45]
Pilot A	Ethics	Validation List	[71]
Pilot A	Ethics	Social and societal impact analysis	[105]
Pilot A	Ethics	List of stop criteria	[64]
Pilot A	Ethics	Informed consent for data use	[15]
Pilot A	Ethics	function creep removed	[76]
Pilot B	Value	Added value	[154]
Pilot B	Value	Application accepted	x
Pilot B	Value	Relevant stakeholder check	[17]
Pilot B	Value	scale up options	[111]
Pilot B	Value	quantitative and qualitative cost/benefit analysis	[94]
Pilot B	Value	business case part of HTA	[25]
Pilot B	Application	Operational and social effects of use	[165]
Pilot B	Application	Expert sessions	[160]
Pilot B	Application	UX and UI measured analysed and documented	[106]
Pilot B	Application	Trainings needs	x
Pilot B	Application	Changes of protocol determined	x
Pilot B	Technology	Data Storage available through data standards	x
Pilot B	Accountability	definitive risk-benefit analysis	[130]
Pilot B	Accountability	DPIA	[5]
Pilot B	Accountability	Product dossier converted from IMDD	[92]
Pilot B	Accountability	updated clinical evaluation report	[71]
Pilot B	Accountability	Information security risk classifaction	[142]
Pilot B	Ethics	Analysis of proportionality	[116]
Pilot B	Ethics	Effects on treatment relationship assesment	[19]
Pilot B	Ethics	Broader scientific application	x
Pilot B	Ethics	function creep removed	[76]
Implementation	Value	justification of utility and need (social returns)	[10]

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Phase	Domain	Deliverable	Ref
Implementation	Value	no change of functionality check	x
Implementation	Value	Stakeholders have been involved	x
Implementation	Value	Funding agreements	x
Implementation	Value	Definitive version of business case	[135]
Implementation	Value	Measuring and monitoring system in place	x
Implementation	Application	Implementation plan	[35]
Implementation	Application	Information and promotion	x
Implementation	Application	Application meets functional and other standards	x
Implementation	Application	final acceptance test completed	x
Implementation	Application	end users are trained	x
Implementation	Application	Functional manuals in place	x
Implementation	Application	Procedures and governance for safe use	[91]
Implementation	Application	Functional management & support available	x
Implementation	Technology	Application has been integrated into architecture	x
Implementation	Technology	Kill switch in place	x
Implementation	Technology	Technical management & support available	x
Implementation	Accountability	Governance and agreements with external suppliers	x
Implementation	Accountability	Released application	x
Implementation	Accountability	Updated Risk management plan	[122]

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Phase	Domain	Deliverable	Ref
Implementation	Accountability	new DPIA for production	[5]
Implementation	Accountability	post-market clinical follow-up plan	[47]
Implementation	Accountability	informaton security for production	[142]
Implementation	Accountability	definitive privacy statement and terms & conditions	[45]
Implementation	Accountability	post-market surveillance plan	[95]
Implementation	Ethics	Desired Bias assessed	[132]
Implementation	Ethics	Limits of use	x
Implementation	Ethics	Unforseen consequences considered	x
Implementation	Ethics	Clear responsibilities for correct use	x
Use	Value	Monitoring for expected added value	[154]
Use	Value	Monitoring for changed functionality	x
Use	Value	Monitoring for positive and negative consequences	x
Use	Value	plan for (inter)national scale-up	[111]
Use	Value	Business case scale-up	[135]
Use	Application	Evaluation and lessons learned	x
Use	Application	Continous test and evaluation cycle	[14]
Use	Application	Updated functional manuals	x
Use	Application	plan for transitioning to new work practice	x
Use	Technology	Technical plan for scale-up	[111]
Use	Technology	Technical manuals & documentation	x
Use	Accountability	post-market surveillance plan	[95]

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Phase	Domain	Deliverable	Ref
Use	Accountability	Continous evaluation of clinical use experience	[89]
Use	Accountability	DPIA when changes occur	[5]
Use	Accountability	Periodic recalibration of risk classification for information security	[142]
Use	Ethics	Monitoring level of trust	[109]
Use	Ethics	Monitoring effect on the care relationship	[19]
Use	Ethics	Continous identification of undesired bias	[132]
Use	Ethics	Re-evalution in place for circumstances where limits of use are exceeded	x
Use	Ethics	Continous monitoring of possible future difficulties	x

Table B.2: Overview of the different Concepts used in the phase PDDs

Domain	Deliverable	Ref
IDEA DESCRIPTION	At the hand of the SCQ method the solution is described, including any alternatives	[101]
TANGIBLE VALUE AT THE HAND OF END USER	The added value described at the hand of the final user their perspective	[154]
POTENTIAL STAKE-HOLDER LIST	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have	[151]
SOLUTION LIFECYCLE	A description of the phases the solution will go through and its final outcome	[164],[32]

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Domain	Deliverable	Ref
BUSINESS CASE OUTLINE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
PERSONAS	A fictional description of the needs and expectations of the earlier defined stakeholders	[54]
PROCESS EXPLORATION	Analysis of the current workflow	[83]
DATA AVAILABILITY	Analysis whether enough information is available for the AI system to run	x
STRATEGIC AMBASSADOR	Person who carries the responsibilities for the project and actively supports the project	x
FEASIBILITY & CONDITIONS FOR RESPONSIVE USE	A description of the achievability of the project and how to achieve this in an ethical matter	x
RISK SCAN	An identification of risk areas and issues that might occur with the project	x
DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
CONTRACTUAL ARRANGEMENTS	The different agreements made between the project team, hospital and potential software development company	x
IMPACT ON INEQUALITIES	Defenition of positive and negative consequences the final product and its development can have on equalities to prevent bias	[151]
ANALYSIS USEFULNESS IN MEDICAL PRACTICE	Analysis of the usefulness of the final application in the medical field	[40]
BEGELEIDINGSETHIEK	Method to aid in applying technology in practice in an ethically responsible manner	[96]

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Domain	Deliverable	Ref
RESEARCH QUESTION	Full objective of the project on what to study, scope and potential scale-up	[136]
USER STORIES	Short stories which can act as requirements for the AI system	[52]
STAKE-HOLDER ANALYSIS	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
VALORISA-TION STRATEGY	The strategy which is described at the hand of where action is taken place, its objectives and areas	[82]
BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
MARKET SCAN	Analysis of how many customers there might be for the project and main competitors	[41]
CLIENT/PATIENT JOURNEY	The steps which the patient or healthcare provider will take or undergo whenever using the AI system	[39]
PROTOTYPE SOLUTION	A mockup or partly working product to display the functionality	x
DATA END REPORT	Analysis of the available data, reliability and quality of the produced data, a data dictionary and validation of available data	x
START ARCHI-TECTURE	Visualization of the software its infrastructure	[18]
DEVELOP-MENT PLAN	Proposed planning of the different development stages of the AI system	[119]
LIABILITY ANALYSIS	Analysis of which legal requirements the AI system has to meet	x
MEDICAL DEVICE ASSESSMENT	The determination of whether the AI system can be seen as a medical device or as a regular AI system	[61]
RISK MAN-AGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]

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Domain	Deliverable	Ref
RISK-BENEFIT ANALYSIS	Analysis with the aim of whether the risks weigh up against the positive and negative effects of the AI system	[130]
UPDATED DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
DATA MINIMIZED OR AGREGATED	Non essential data has been removed	[114]
DETERMINED MANUFAC-TURER	The STAKEHOLDER who will develop the AI system	x
CLINICAL EVALUATION PLAN	Planning on how the evaluation in the clinical field will be done	[71]
INFORMA-TION SECURITY RISK CLASSI-FICATION	Value assigned to how large the risk is detected in the RISK ANALYSIS for the information security	[142]
ETHICS BY DESIGN	Openly known concepts which guarantee an ethical use of the AI system	[104]
PROOF OF CONSENT AND AUTONOMY REQUIRED	Signed form by patients who partake in the use of the AI system	x
SUPPORT FOR ACCEPTABLE HUMAN IN-TERACTION	Knowledge and skills needed by the different STAKEHOLDERS who use the Ai system	[151]
DEVELOPED AI SYSTEM	The working AI system	x
DEMOS OF MVP	Demonstrations given at the hand of the MINIMAL VIABLE PRODUCT	x
REFINED BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]

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Domain	Deliverable	Ref
EXPERT SESSIONS WITH AMBASSADORS	Feedback is retrieved at the hand of experts on the subject	[160]
UX AND UI REQUIREMENTS	Necessities on how the AI system should look and how a user should be able to interact with the system	[150]
TRAINING	A method taught to different STAKEHOLDERS on how to use the DEVELOPED APPLICATION	x
DATA COLLECTION, MODEL AND REPOSITORY	Place where the DATA is stored	[114]
ARCHITECTURE MAP	Visualization of the software its infrastructure	[18]
DEFINITIVE ALGORITHM	The final algorithm the AI system uses	x
FUNCTIONAL APPLICATION/FINISHED MVP	A fully working AI system, acting as a minimal viable product for testing	x
DEFINITIVE RISK CLASS	Value assigned to how large the risk in detected in the RISK ANALYSIS for the overall AI system	[142]
CERTIFICATION PLAN	A planning on how to meet the requirements for the different certifications needed for the AI system	[11]
UPDATED RISK MANAGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]
UPDATED RISK-BENEFIT ANALYSIS	Analysis with the aim whether the risks weigh up against the positive and negative effects of the AI system	[130]

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Domain	Deliverable	Ref
CLINICAL EVALUATION REPORT	Performance test at the hand of a literature study and test in the development phase	[71]
INVESTIGATIONAL MEDICAL DEVICE DOSSIER (IMDD)	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
VERIFICATION OF NORMS AND VALUES	Test whether the system test applies to the different ethical values	[148]
APPLICATION RESPECTS USERS AUTONOMY	Validation whether the application does allow for the user to make its own decision and does not get overruled	[60]
DUE DILIGENCE CHECK	Analysis of the AI system on economic, legal, fiscal and financial aspects	[13]
ADDED VALUE	Extra advantages the AI system has at the hand of new functionalities	[154]
DEMOS OF APPLICATION	Demonstrations given at the hand of the AI system	x
available FINANCIAL RESOURCES	Amount of money available for the development and implementation of the AI system	x
VALIDATION PLAN	Plan on how to measure the ADDED VALUE	[71]
INCENTIVE ANALYSIS	Analysis of performance and effort expectancy, social influence and facilitating conditions	[55]
EXPERT SESSIONS WITH USERS	Expert sessions are held with the users of the AI SYSTEM to receive feedback on its use, UI and UX	[160]
UI EVALUATION	Testing whether the user interaction upholds to set standards	[106]

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Domain	Deliverable	Ref
TRAINING AND SCHOOLING	Educational material on how to use the AI system	x
DATA STORAGE	Location where the data is safely kept	x
SCALABLE DEVELOPMENT ENVIRONMENT	The place where the DEFINITIVE APPLICATION will run	x
DEFINITIVE APPLICATION	Final AI system	x
CLINICAL EVALUATION REPORT WITH TECHNICAL PERFORMANCE	Validation on the accuracy of the algorithm in the medical field	[71]
RISK CLASSIFICATION INFORMATION SECURITY	Value assigned to how large the risk in detected in the RISK ANALYSIS for the information security	[142]
DEFINITIVE IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
WMO CLASSIFICATION	Validation where the AI system is a medical device	[29]
DEFINITIVE PRIVACY STATEMENT	Document for the patients which educates them on how their privacy is kept	[45]
VALIDATION LIST	List of criteria in which the RELEASED APPLICATION has to apply to	[71]
SOCIAL AND SOCIETAL IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have on society	[105]

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Domain	Deliverable	Ref
LIST OF STOP CRITERIA	List of occurrences whenever the AI system no longer can be used	[64]
INFORMED CONSENT FOR DATA USE	Document where a patient agrees with using the AI system	[15]
FUNCTION CREEP REMOVED	Functionality within the AI system which is no longer wanted or was never in the design and is unwanted	[76]
APPLICATION ACCEPTED	Application gets accepted by the customer	x
RELEVANT STAKE-HOLDER CHECK	A check whether still all STAKEHOLDERS are relevant or extra stakeholders have to be included	[17]
SCALE UP OPTIONS	Analysis to see how and where there are possibilities for the AI system to become larger	[111]
QUANTITA-TIVE AND QUALITATIVE COST/BENEFIT ANALYSIS	Measurements of different demographics about the use of the AI SYSTEM in pilot B. Influences the decision-making process	[94]
BUSINESS CASE PART OF HTA	Outline of the proposed changes and TANGIBLE VALUE for the health technology assessment	[25]
OPERA-TIONAL AND SOCIAL EFFECTS OF USE	Consequences the AI SYSTEM caused by its use on operational and social level	[165]
EXPERT SESSIONS	Session with people with a lot of knowledge in the domain which will validate the processes and the application	[160]
UX AND UI MEASURED ANALYSED AND DOCU-MENTED	Measurements of the user experience and the user interface and their usability, looks etc.	[106]

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Domain	Deliverable	Ref
TRAININGS NEEDS	Necessities for educating STAKEHOLDERS	x
CHANGES OF PROTOCOL DETERMINED	Determination whether current processes have to be changed	x
DATA STORAGE available THROUGH DATA STANDARDS	A check whether the DATA STORAGE upholds previously set standards	x
DEFINITIVE RISK-BENEFIT ANALYSIS	Analysis with the aim whether the risks weigh up against the positive and negative effects of the AI system	[130]
PRODUCT DOSSIER CONVERTED FROM IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
UPDATED CLINICAL EVALUATION REPORT	Validation on the accuracy of the algorithm in the medical field	[71]
ANALYSIS OF PROPORTION-ALITY	Determination whether the use of the AI SYSTEM weighs up against its downfalls	[116]
EFFECTS ON TREATMENT RELATION-SHIP ASSESSMENT	Measurements about the relationship between the healthcare provider and the patients	[19]
BROADER SCIENTIFIC APPLICATION	Extension study to check whether the AI FINAL APPLICATION is able to be used for other problems	x

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Domain	Deliverable	Ref
JUSTIFICATION OF UTILITY AND NEED (SOCIAL RETURNS)	Reasoning about why the AI SYSTEM should be used and how society can profit from its use	[10]
NO CHANGE OF FUNCTIONALITY CHECK	Analysis whether no FUNCTION CREEP has occurred	x
STAKEHOLDERS HAVE BEEN INVOLVED	A final check whether all stakeholders are part of the STAKEHOLDER ANALYSIS	x
FUNDING AGREEMENTS	Contractual agreements on the payments for the development, testing and pilots of the AI system	x
DEFINITIVE VERSION OF BUSINESS CASE	Outline of the created changes and TANGIBLE VALUE of the RELEASED APPLICATION	[135]
MEASURING AND MONITORING SYSTEM IN PLACE	Different systems which aid to the different monitoring processes which aid the AI SYSTEM when fully integrated	x
IMPLEMENTATION PLAN	Planning of the different stages in which the FINAL APPLICATION will be implemented in the current environment	[35]
INFORMATION AND PROMOTION	Educational content and promotional material for the different STAKEHOLDERS on the FINAL APPLICATION	x
APPLICATION MEETS FUNCTIONAL AND OTHER STANDARDS	A check whether the application upholds previous set standards	x

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Domain	Deliverable	Ref
FINAL ACCEPTANCE TEST COMPLETED	The last validation of the FINAL APPLICATION	x
END USERS ARE TRAINED	The STAKEHOLDERS which have to use the FINAL APPLICATION have received the correct education	x
FUNCTIONAL MANUALS IN PLACE	Written documentation on how to use the AI system	x
PROCEDURES AND GOVERNANCE FOR SAFE USE	Different rules and processes are in place not to exceed the	[91]
FUNCTIONAL MANAGEMENT & SUPPORT available	MANUALS and INFORMATION are available for the end user	x
APPLICATION HAS BEEN INTEGRATED INTO ARCHITECTURE	The AI SYSTEM is integrated into the EXISTING ARCHITECTURE	x
KILL SWITCH IN PLACE	A method to immediately stop the AI system if necessary	x
TECHNICAL MANAGEMENT & SUPPORT available	STAKEHOLDERS which aid the healthcare providers or patients in using the FINAL APPLICATION	x
GOVERNANCE AND AGREEMENTS WITH EXTERNAL SUPPLIERS	Contractual agreements with the development party which will create the AI system	x
RELEASED APPLICATION	The FINAL APPLICATION fully used in the healthcare domain	x

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Domain	Deliverable	Ref
NEW DPIA FOR PRODUCTION	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
POST-MARKET CLINICAL FOLLOW-UP PLAN	Initiated to document updates happening as the AI system is running in the clinical field. It reports patients safety and performance	[47]
INFORMATON SECURITY FOR PRODUCTION	Procedures and protection for data	[142]
DEFINITIVE PRIVACY STATEMENT AND TERMS & CONDITIONS	Contractual agreement on the participation of the patient in the RELEASED APPLICATION	[45]
DESIRED BIAS ASSESSED	Analysis of the bias within the AI system and how this is kept within limits	[132]
LIMITS OF USE	Rules on for which functionalities the AI system can be used and where its limits are	x
UNFORSEEN CONSE-QUENCES CONSIDERED	Analysis of new issues	x
CLEAR RESPONSIBIL-ITIES FOR CORRECT USE	A set of rules which limit the use of the AI system to ensure it is not used for non-intended purposes	x
MONITORING FOR EXPECTED ADDED VALUE	Controlling whether the AI system upholds to the expected value over time	[154]

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Domain	Deliverable	Ref
MONITORING FOR CHANGED FUNCTIONALITY	Controlling if any FUNCTION CREEP occurred	x
MONITORING FOR POSITIVE AND NEGATIVE CONSEQUENCES	A continuous IMPACT ANALYSIS is done for STAKEHOLDERS	x
PLAN FOR (INTER)NATIONAL SCALE-UP	Planning to increase the scale of the RELEASED APPLICATION	[111]
BUSINESS CASE SCALE-UP	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
EVALUATION AND LESSONS LEARNED	A look back at the entire process to see what went wrong and what parts could have been improved	x
CONTINOUS TEST AND EVALUATION CYCLE	Continous controlling and testing of the RELEASED APPLICATION	[14]
UPDATED FUNCTIONAL MANUALS	Written documentation on how to use the AI system	x
PLAN FOR TRANSITIONING TO NEW WORK PRACTICE	Planning on the transition for taking the new AI system into place	x
TECHNICAL PLAN FOR SCALE-UP	A predetermined plan on how to allow the AI system to function on a larger scale	[111]

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Domain	Deliverable	Ref
TECHNICAL MANUALS & DOCUMENTATION	Written documentation on the technical details of the AI system	x
POST-MARKET SURVEILLANCE PLAN	Controlling on how the AI system functions	[95]
CONTINOUS EVALUATION OF CLINICAL USE EXPERIENCE	Controlling of how patients and healthcare providers feel about using the AI system	[89]
DPIA WHEN CHANGES OCCUR	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
PERIODIC RE-CALIBRATION OF RISK CLASSIFICATION FOR INFORMATION SECURITY	Value assigned to how large the risk is detected in the RISK ANALYSIS for the overall AI system	[142]
MONITORING LEVEL OF TRUST	Controlling the trust patients and healthcare providers have in the AI system	[109]
MONITORING EFFECT ON THE CARE RELATIONSHIP	controlling of the relationship between patients and healthcare providers	[19]
CONTINOUS IDENTIFICATION OF UNDESIRED BIAS	Controlling bias which may occur due to training data becoming outdated	[132]

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Domain	**Deliverable**	**Ref**
RE-EVALUTION IN PLACE FOR CIRCUM-STANCES WHERE LIMITS OF USE ARE EXCEEDED	A re-evaluation for when the LIMITS OF USE are exceeded. Evaluates whether it is still viable to use the AI SYSTEM	x
CONTINOUS MONITORING OF POSSIBLE FUTURE DIFFICULTIES	Controlling for mistakes in the AI system or its functionality which can occur in the (near) future	x

Appendix C

PDD overview

This appendix shows the first iteration of PDDs created for the methods used by the UMCU.

For a better view, go to: https://drive.google.com/file/d/1kpo1u8M4hUY6O5KmG3b9JozdJH
view?usp=sharing

C.1 PDD Zenya

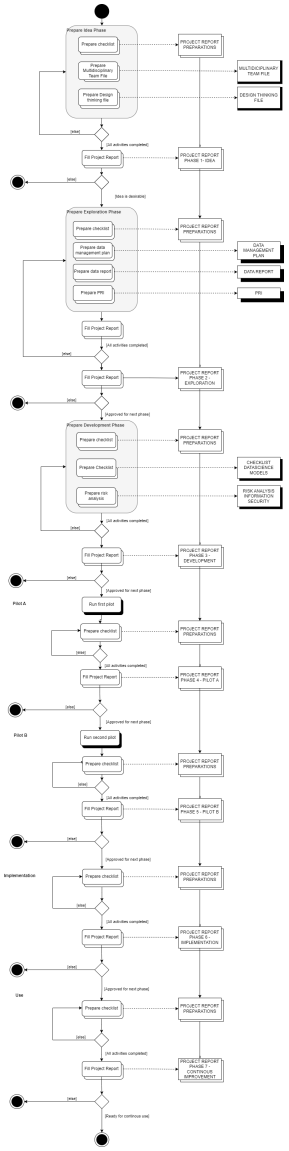

Figure C.1: PDD Zenya platform

C.1.1 Activity Table

Table C.2: Activity table Zenya

Activity	Sub Activity	Description
Prepare Idea Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Prepare multidisciplinary file	
	Prepare design thinking file	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Exploration Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Prepare data management plan	
	prepare data report	
	prepare PRI	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Development Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Pepare checklist	
	Prepare risk analysis	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Run first pilot		A pilot is run without real patients or within a safe environment

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Activity	Sub Activity	Description
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Run Second pilot		The previously created and trained algorithm is tested on real patient data
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report

C.1.2 Concept Table

Table C.3: Concept table Zenya

Concept	Description
DELIVERABLES	Different information which has to be described by the researcher or in combination with Digital Health for the project to succeed
PROJECT REPORT PREPARATIONS PHASE 1	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
MULTIDISCIPLINARY TEAM FILE	A distribution of team members among different responsible provides an overview of the team and Digital Health
DESIGN THINKING FILE	Provides a template with elaborations of multiple concepts part of PROJECT REPORT PHASE 1 to assist the initiative
PROJECT REPORT PHASE 1	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 1 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 2	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
DATA MANAGEMENT PLAN	A description of which data will be collected, how this data will be collected, where it will be stored, and how it is secured.
DATA REPORT	Overview of information, such as a dashboard, about the data retrieved and how it has been processed
PRI	A predictive risk inventory done to identify risks
PROJECT REPORT PHASE 2	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 1 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 3	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department

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Concept	Description
CHECKLIST DATA SCIENCE MODELS	A checklist which can be used to measure the use of the AI system and its features
RISK ANALYSIS INFORMATION SECURITY	An analysis of the potential risks when collecting, saving, and processing data
PROJECT REPORT PHASE 3	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 3 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 4	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 4	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 4 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 5	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 5	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 5 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 6	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 6	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 6 by Digital Health, upon this document, is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 7	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department

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Concept	**Description**
PROJECT REPORT PHASE 7	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 7 by Digital Health, upon this document, is decided whether the project may continue

C.2 PDD Project Report 1

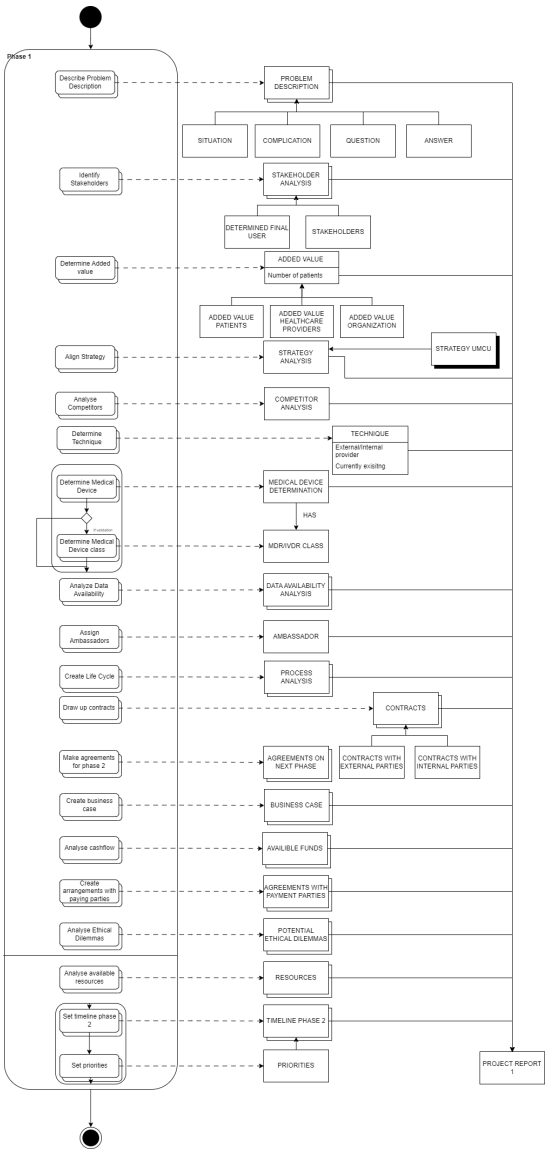

Figure C.2: PDD Phase 1 - Idea

C.2.1 Activity Table

Table C.4: Activity table phase 1

Activity	Sub Activity	Description
Prepare Idea Phase	Describe Problem Description	Describe the PROBLEM DESCRIPTION at the hand of the SCQA method
	Identify Stakeholders	Check which FINAL USERS and other STAKEHOLDERS affects the potential product at the hand of a STAKEHOLDER ANALYSIS
	Determine Added value	Measure the amount of ADDED VALUE the proposed solution will have and if this is positive from the perspective of healthcare providers, the organization and patients. Also, determine the number of patients the AI system might affect.
	Align Strategy	Create a strategy for the idea and check whether the idea fits within the strategy at the UMCU, resulting in a STRATEGY ANALYSIS
	Analyse Competitors	Analyse already existing products and algorithms, resulting in a COMPETITOR ANALYSIS
	Determine Technique	Determine the TECHNIQUE needed for the idea to be suitable
	Determine Medical Device	Get an indication whether the device counts as a medical device, saved as a MEDICAL DEVICE DETERMINATION
	Analyze Data Availability	Analyse potential data which can be used at the hand of the DATA AVAILABILITY ANALYSIS
	Determine Medical Device class	Determine what type of MEDICAL DEVICE CLASS the idea would have if the idea its MEDICAL DEVICE DETERMINATION is true
	Assign Ambassadors	
	Create Life Cycle	Draw the potential AI system its lifecycle to do a PROCESS ANALYSIS

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Activity	Sub Activity	Description
	Draw up contracts	Create CONTRACTS with different external AND internal parties
	Make agreements for phase 2	Create AGREEMENT ON NEXT PHASE within the team and management
	Create business case	Create a first sketch of the BUSINESS CASE
	Analyse cashflow	Describe the AVAILABLE FUNDS for the project
	Create arrangements with paying parties	Create AGREEMENTS WITH PAYMENT PARTIES such as insurers which can pay for extra provided care if necessary
		Analyse which POTENTIAL ETHICAL DILEMMAS you might encounter during the process
	Analyse available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create timeline	Create a TIMELINE for PHASE 2
	Set priorities	Determine which PRIORITIES certain activities might have within the next phase
	Artificial impact assessment	

C.3 PDD Project Report 2

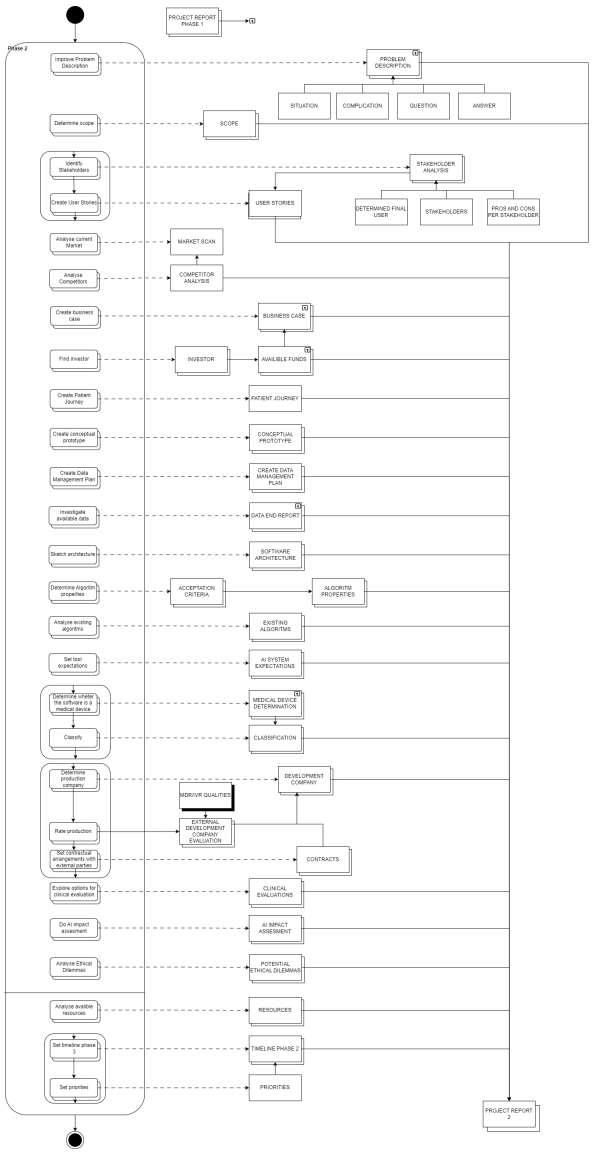

Figure C.3: PDD Phase 2 - Exploration

C.3.1 Activity Table

Table C.5: Activity table exploration phase

Activity	Sub Activity	Description
Prepare Exploration Phase	Improve problem description	Improve the PROBLEM DESCRIPTION create in the PROJECT REPORT PHASE 1 at the hand of the SCQA method
	determine scope	Determine the SCOPE the project will act within
	Identify stakeholders	Hold a STAKEHOLDER ANALYSIS, determining people who will influence the project and its users
	create user stories	Create USER STORIES at the hand of the different stakeholders found in the STAKEHOLDER ANALYSIS
	analyse current market	Analyse the current market in a MARKET SCAN
	Create business case	Update the BUSINESS CASE at the hand of the BUSINESS CASE created in PROJECT REPORT PHASE 1
	analyse competitors	Analyse other organizations which have a similar product at the hand of a COMPETITOR ANALYSIS
	find investor	Update whether there is a set INVESTOR and the AVAILABLE FUNDS
	create patient journey	Create a sketch of the PATIENT JOURNEY
	create conceptual prototype	Set up a CONCEPTUAL PROTOTYPE
	create data management plan	Create a DATA MANAGEMENT PLAN
	investigate available data	Set up a DATA END REPORT at the hand of the DATA AVAILABILITY ANALYSIS from PROJECT REPORT PHASE 1
	sketch architecture	Set up a first version of the SYSTEM ARCHITECTURE
	determine algorithm properties	Determine the ALGORITHM PROPERTIES and the ACCEPTATION CRITERIA the final AI system has to adhere to

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Activity	Sub Activity	Description
	analyse existing algorithms	Analyse any EXISTING ALGORITHMS which can be reused for the purpose of the project
	set tool expectations	Create the AI SYSTEM EXPECTATIONS
		Indicate whether the device counts as a medical device, saved as a MEDICAL DEVICE DETERMINATION
	classify software	Determine what type of MEDICAL DEVICE CLASS the idea would have if the idea its MEDICAL DEVICE DETERMINATION is true
	determine production company	Determine the DEVELOPMENT COMPANY
	rate production	If the DEVELOPMENT COMPANY is an external party, determine whether it suffices to the MDR/IVR QUALITIES in an EXTERNAL DEVELOPMENT COMPANY EVALUATION
	set contractual arrangements with external parties	Create CONTRACTS with external DEVELOPMENT COMPANY
	explore options for clinical evaluation	Check how a CLINICAL EVALUATION can take place to test the AI system
	do AI impact assessment	Create an AI IMPACT ASSESSMENT
	Analyse ethical dilemmas	Update the POTENTIAL ETHICAL DILEMMAS which might take place from PROJECT REPORT PHASE 1
	analyse available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create timeline	Create a TIMELINE for PHASE 3
	set priorities	Determine which PRIORITIES certain activities might have within the next phase

C.4 PDD Project Report 3

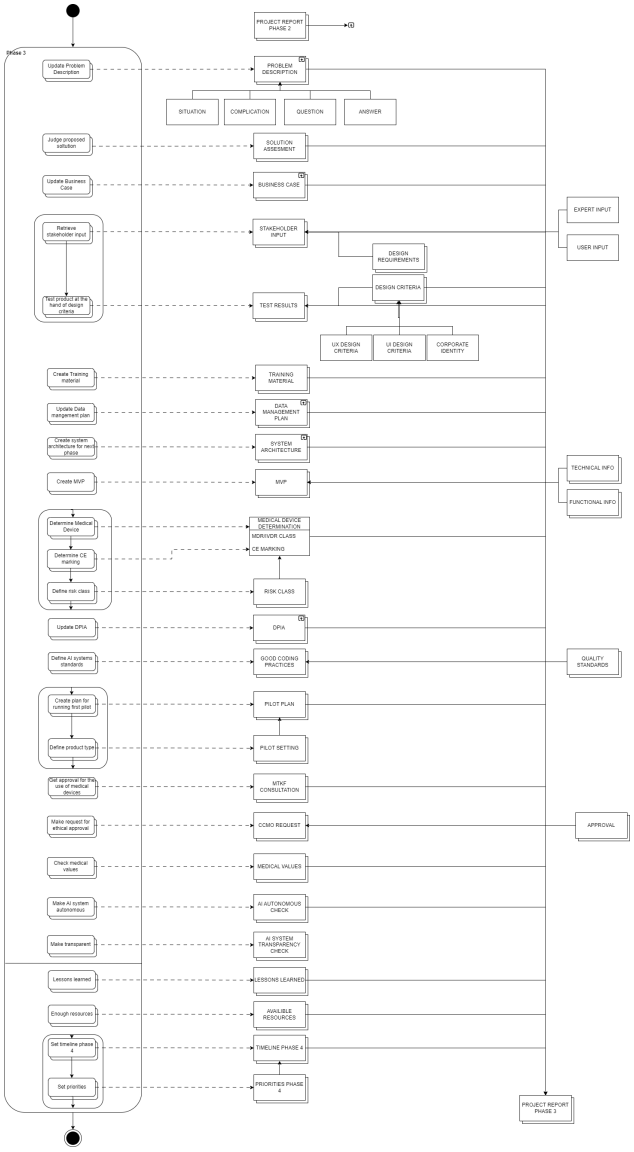

Figure C.4: PDD Phase 3 - Development

C.4.1 Activity Table

Table C.6: Activity table development phase

Activity	Sub Activity	Description
Prepare Development Phase	Update problem description	Improve the PROBLEM DESCRIPTION create in the PROJECT REPORT PHASE 2 at the hand of the SCQA method
	judge proposed solution	A SOLUTION ASSESSMENT is done at the hand of presenting the potential solution at the hand of demos
	update business case	Update the BUSINESS CASE at the hand of the BUSINESS CASE created in PROJECT REPORT PHASE 2 and discuss it with the business office
	retrieve stakeholder input	Receive DESIGN REQUIREMENTS at the hand of EXTERNAL STAKEHOLDER INPUT and INTERNAL STAKEHOLDER INPUT
	test product at the hand of design criteria	Test the potential solution at the hand of the set DESIGN REQUIREMENTS
	create training material	Create TRAINING MATERIAL for users
	update data management plan	Update the DATA MANAGEMENT PLAN, created in PROJECT REPORT PHASE 2
	create system architecture	Create the SYSTEM ARCHITECTURE at the hand of the sketched SYSTEM ARCHITECTURE in PROJECT REPORT PHASE 2
	create MVP	Create the MVP
	determine whether medical device	Update the MEDICAL DEVICE DETERMINATION
	define risk class	Set the RISK CLASS for the MEDICAL DEVICE DETERMINATION
	determine if CE marking	Determine whether CE MARKING is necessary for the potential solution
	Update DPIA	Update the DPIA

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Activity	Sub Activity	Description
	define AI systems standards	Define whether the proposed solution applies according to GOOD CODING PRACTICES and its QUALITY STANDARDS
	create plan for pilot	Create a PILOT PLAN
	define product type	Define the PILOT SETTING in which the pilot will take place
	Get approval for check of medical devices	Get an MKTF CONSULTATION to approve the use of the proposed solution
	Make a request for ethical approval	Have the potential solution and the PILOT PLAN checked at the CCMO
	check medical values	Check whether the potential solution applies to the MEDICAL VALUES set
	make AI system autonomous	Check whether the potential solution is autonomous for the end users
	Make AI transparent	Check whether the potential solution is transparent enough and what sensitive data is used at the hand of an AI SYSTEM TRANPARENCY CHECK
	Document lessons learned	Document the LESSONS LEARNED during this phase
	Determine enough resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Set timeline for phase 4	Create a TIMELINE for the next phase
	Set priorities for phase 4	Determine which PRIORITIES certain activities might have within the next phase

C.5 PDD Project Report 4

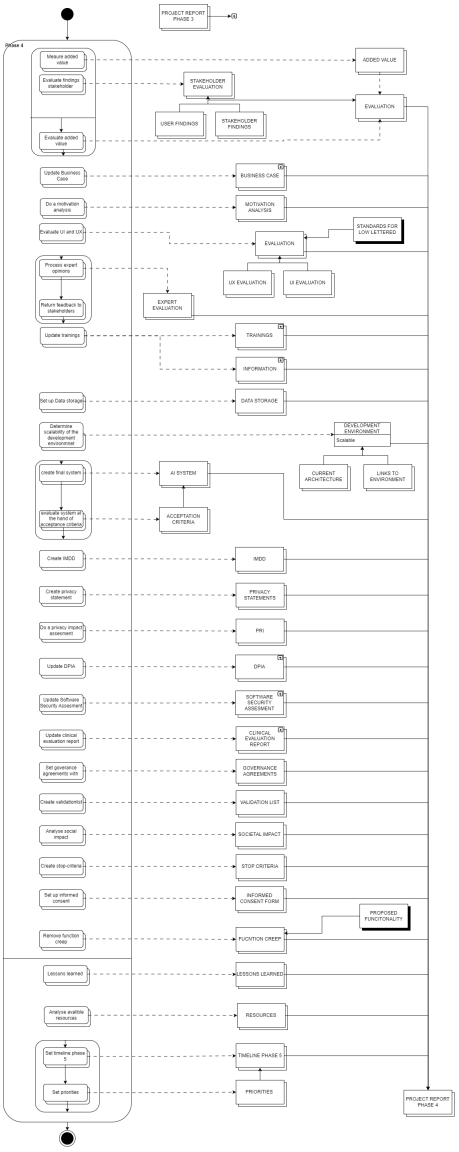

Figure C.5: PDD Phase 4 - Pilot A

C.5.1 Activity Table

Table C.7: Activity table pilot A phase

Activity	Sub Activity	Description
Prepare Pilot A Phase	measure added value	Measure the ADDED VALUE during the pilot
	evaluate added value	Evaluate the ADDED VALUE and the STAKEHOLDER EVALUATION
	evaluate findings stakeholder	Evaluate the USER FINDINGS and STAKEHOLDER FINDINGS
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 3
	hold motivation analysis	Create a MOTIVATION ANALYSIS at the hand of the use of the proposed solution in the next phase
	evaluate UI and UX	Evaluate the UI and UX and check if it upholds the STANDARDS FOR LOW LETTERED
	process expert opinions	Hold expert sessions and evaluate their opinions
	return feedback to stakeholders	Return the EXPERT EVALUATION to the stakeholders
	update pieces of training	Update the TRAININGS and INFORMATION for the proposed solution
	Set up data storage	Set up a DATA STORAGE environment for patient data
	measure scalability	Determine whether the DEVELOPMENT ENVIRONMENT is fit for scale-up
	create final system	create the final AI SYSTEM
	evaluate system at the hand of acceptance criteria	Evaluate the AI SYSTEM at the hand ACCEPTATION CRITERIA
	create IMDD	Create the IMDD
	create privacy statement	Create a PRIVACY STATEMENT for clinical use
	do a PRI	Do a PRI

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Activity	Sub Activity	Description
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 3
	update software security assessment	Update the SOFTWARE SECURITY ASSESSMENT created in PROJECT REPORT PHASE 3
	update clinical evaluation report	Update the CLINICAL EVALUATION REPORT created in PROJECT REPORT PHASE 3
	create validation list	Create a VALIDATION LIST with the expected results of the AI SYSTEM
	Analyse social impact	Analyse the SOCIETAL IMPACT of the AI SYSTEM
	create stop criteria	Create a list of STOP CRITERIA
	Set up informed consent	Set up an INFORMED CONSENT FORM for patients
	remove function creep	Remove FUNCTION CREEP at the hand of the PROPOSED FUNCTIONALITY
	lessons learned	Document the LESSONS LEARNED during this phase
	check if necessary resources are available	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	create timeline for phase 5	Create a TIMELINE for the next phase
	Set priorities for phase 5	Determine which PRIORITIES certain activities might have within the next phase

C.6 PDD Project Report 5

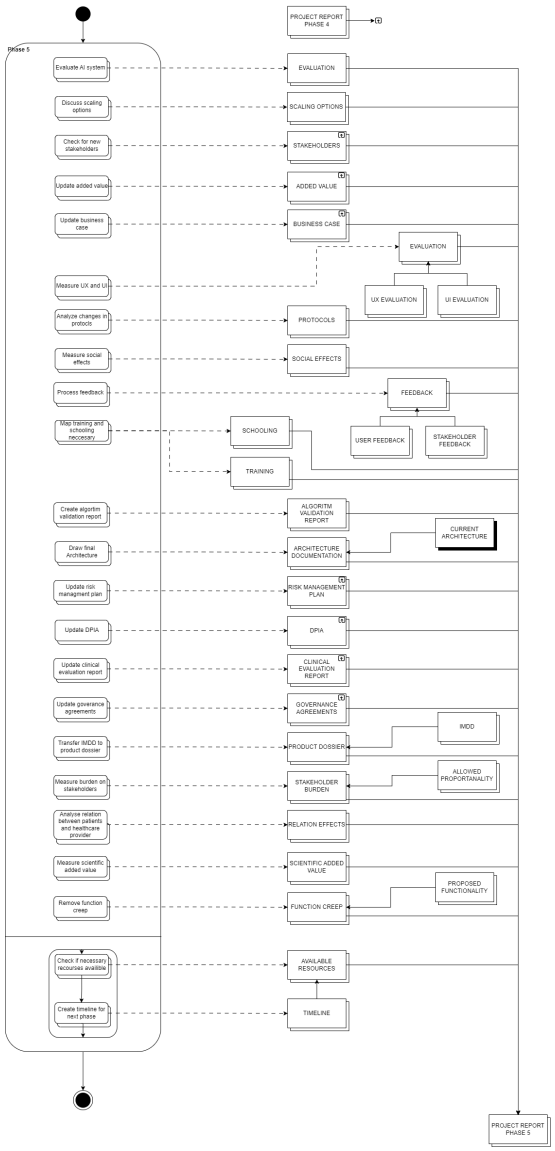

Figure C.6: PDD Phase 5 - Pilot B

C.6.1 Activity Table

Table C.8: Activity table pilot B phase

Activity	Sub Activity	Description
Prepare Pilot B Phase	evaluate AI system	Evaluate the AI SYSTEM
	Discuss scaling options	Do a check of the SCALING OPTIONS of the AI SYSTEM
	check for new stakeholders	Check whether the STAKEHOLDERS are still relevant or if new STAKEHOLDERS have come into the picture
	update added value	Update the ADDED VALUE set in PROJECT REPORT PHASE 4 with the measurement from current phase
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 4
	measure UI and UX	Evaluate the UX and UI
	analyze changes in protocols	Check whether the current PROTOCOLS have changed with the use of the AI SYSTEM
	measure social effects	Measure SOCIAL EFFECTS at the hand of the PATIENT JOURNEY created in previous phases
	process feedback	Process the USER FEEDBACK and STAKEHOLDER FEEDBACK
	map training and schooling necessary	Map what SCHOOLING and TRAININGS are needed for the use of the AI SYSTEM
	create algorithm validation report	A data scientist creates an ALGORITHM VALIDATION REPORT
	draw final architecture	Create an ALGORITHM DOCUMENTATION at the hand of the CURRENT ARCHITECTURE
	update risk management plan	Update the RISK MANAGEMENT PLAN
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 4

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Activity	Sub Activity	Description
	update clinical evaluation report	Update the CLINICAL EVALUATION REPORT created in PROJECT REPORT PHASE 4
	update governance agreements	Update GOVERNANCE AGREEMENTS
	transfer IMDD to product product dossier	Transfer the IMDD to the PRODUCT DOSSIER
	measure burden on stakeholders	Measure the STAKEHOLDER BURDEN
	Analyse the relation between patients and healthcare providers	Analyse the RELATIONAL EFFECT between patients and healthcare providers during the use of the AI SYSTEM
	measure scientific added value	Measure the SCIENTIFIC ADDED VALUE of the AI SYSTEM
	remove function creep	Remove FUNCTION CREEP at the hand of the PROPOSED FUNCTIONALITY
	check if necessary resources are available	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create a timeline for the next phase	Create a TIMELINE for the next phase

C.7 PDD Project Report 6

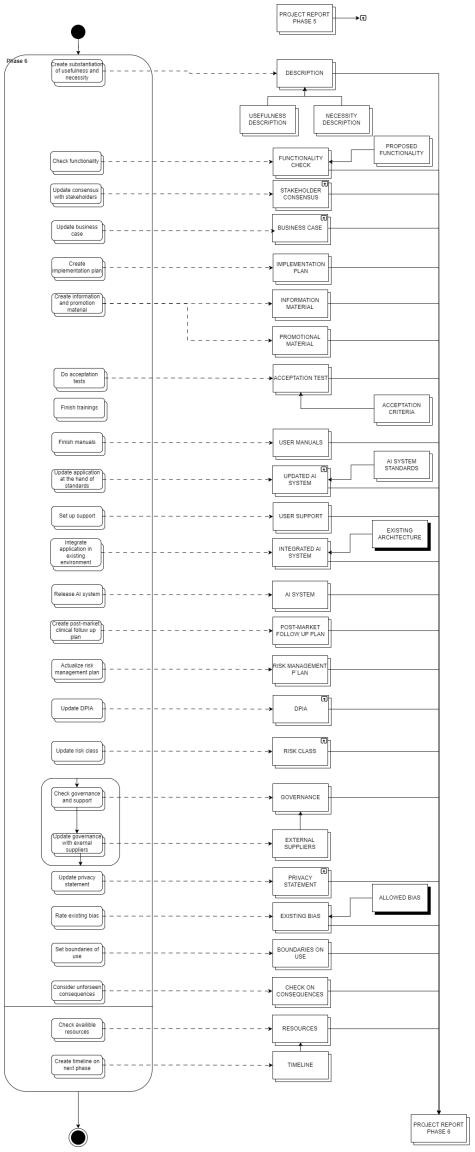

Figure C.7: PDD Phase 6 - Implementation

C.7.1 Activity Table

Table C.9: Activity table implementation phase

Activity	Sub Activity	Description
Prepare Implementation Phase	create substantiation of usefulness and necessity	Create a public USEFULNESS DESCRIPTION and a NECESSITY DESCRIPTION
	check functionality	Check whether the functionality of the AI SYSTEM still upholds the PROPOSED FUNCTIONALITY
	update consensus with stakeholders	Update STAKEHOLDER CONSENSUS with
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 5
	create implementation plan	Create an IMPLEMENTATION PLAN
	create information and promotion material	Create INFORMATION MATERIAL and PROMOTION MATERIAL for the use of the AI SYSTEM
	do acceptation tests	Do ACCEPTATION TESTS at the hand of the ACCEPTATION CRITERIA
	finish trainings	Finish the TRAININGS created in PROJECT REPORT PHASE 5
	finish manuals	Finish the MANUALS created in PROJECT REPORT PHASE 5
	update application at the hand of standards	Update the AI SYSTEM at the hand of the AI SYSTEM STANDARDS
	Set up support	Set up USER SUPPORT for the use of the AI SYSTEM
	integrate application in existing environment	Integrate the AI SYSTEM in the EXISTING ARCHITECTURE
	release AI system	Officially release the AI SYSTEM

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Activity	Sub Activity	Description
	create post/market clinical follow up plan	Create the POST-MARKET FOLLOW UP PLAN
	actualize risk management plan	Update the RISK MANAGEMENT PLAN created in PROJECT REPORT PHASE 5
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 5
	update risk class	Update the RISK CLASS created in PROJECT REPORT PHASE 5
	Update governance with external suppliers	Update the GOVERNANCE WITH EXTERNAL SUPPLIERS created in PROJECT REPORT PHASE 5
	update privacy statement	Update the PRIVACY STATEMENT created in PROJECT REPORT PHASE 5
	rate existing bias	Rate the EXISTING BIAS at the hand of the ALLOWED BIAS
	set boundaries on use	Set BOUNDARIES ON USE for the use of the AI SYSTEM
	consider unforeseen consequences	Make a consideration of UNFORESEEN CONSEQUENCES
	check available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create a timeline for the next phase	Create a TIMELINE for the next phase

C.8 PDD Project Report 7

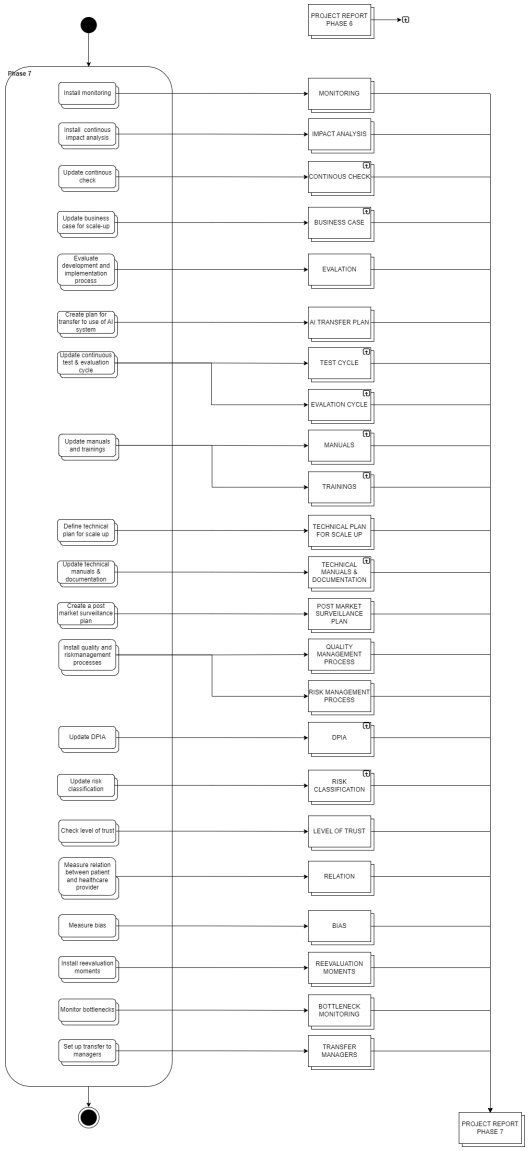

Figure C.8: PDD Phase 7 - Continous Monitoring

C.8.1 Activity Table

Table C.10: Activity table use phase

Activity	Sub Activity	Description
	install continuous impact analysis	Install a CONTINOUS IMPACT ANALYSIS
	update continuous check	Create a CONTINOUS CHECK to determine whether the AI SYSTEM functions according to the PROPOSED FUNCTIONALITY
	update business case for scale-up	Update the BUSINESS CASE when scale-up occurs
	evaluate development and implementation process	Create an EVALUATION OF THE IMPLEMENTATION PROCESS with the different stakeholders
	create a plan for transfer to use of the AI system	Create an AI TRANSFER PLAN for the use of the AI SYSTEM
	update continuous test & evaluation cycle	Update the TEST CYCLE and EVALUATION CYCLE
	update manuals and trainings	Update the TRAININGS and MANUALS after implementation
	define technical plan for scale up	Create a TECHNICAL PLAN FOR SCALE-UP
	update technical manuals & documentation	Update the MANUALS and DOCUMENTATION
	create a post-market surveillance plan	Create POST MARKET SURVEILLANCE PLAN
	install quality and risk management processes	Install QUALITY MANAGEMENT PROCESSES and RISK MANAGEMENT PROCESSES
	update DPIA	When changes occur, update the DPIA
	update risk classification	When changes occur, update the RISK CLASSIFICATION

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Activity	Sub Activity	Description
	check level of trust	Measure the LEVEL OF TRUST by users
	measure the relationship between patient and healthcare provider	Measure the LEVEL OF TRUST by users RELATIONSHIP between healthcare providers and patients
	measure bias	Measure the BIAS which occurs at the hand of the AI system and if it complies with the desired bias
	install reevaluation moments	Install different REEVALUATION MOMENT in which measurements take place
	monitor bottlenecks	Monitor the different bottlenecks at the hand of the AI system and its weaknesses
	Set up transfer to managers	Set up TRANSFER MANAGERS which take over the AI system and its responsibilities

C.9 Concept Table

Table C.11: Overview of the different Concepts used in the phase PDDs

Domain	Deliverable	Ref
ADDED VALUE	Extra advantages the AI system has at the hand of new functionalities	[154]
ANALYSIS OF PROPORTIONALITY	Determination whether the use of the AI SYSTEM weighs up against its downfalls	[116]
ANALYSIS USEFULNESS IN MEDICAL PRACTICE	Analysis of the usefulness of the final application in the medical field	[40]
APPLICATION ACCEPTED	Application gets accepted by the customer	x
APPLICATION HAS BEEN INTEGRATED INTO ARCHITECTURE	The AI SYSTEM is integrated into the EXISTING ARCHITECTURE	x
APPLICATION MEETS FUNCTIONAL AND OTHER STANDARDS	A check whether the application upholds previous set standards	x
APPLICATION RESPECTS USERS AUTONOMY	Validation whether the application does allow for the user to make its own decision and does not get overruled	[60]
ARCHITECTURE MAP	Visualization of the software its infrastructure	[18]
AVAILABLE FINANCIAL RESOURCES	Amount of money available for the development and implementation of the AI system	x
BEGELEIDINGSETHIEK	Method to aid in applying technology in practice in an ethically responsible manner	[96]
BROADER SCIENTIFIC APPLICATION	Extension study to check whether the AI FINAL APPLICATION is able to be used for other problems	x

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Domain	Deliverable	Ref
BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
BUSINESS CASE OUTLINE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
BUSINESS CASE PART OF HTA	Outline of the proposed changes and TANGIBLE VALUE for the health technology assessment	[25]
BUSINESS CASE SCALE-UP	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
CERTIFICATION PLAN	A planning on how to meet the requirements for the different certifications needed for the AI system	[11]
CHANGES OF PROTOCOL DETERMINED	Determination whether current processes have to be changed	x
CLEAR RESPONSIBILITIES FOR CORRECT USE	A set of rules which limit the use of the AI system to ensure it is not used for non-intended purposes	x
CLIENT/PATIENT JOURNEY	The steps which the patient or healthcare provider will take or undergo whenever using the AI system	[39]
CLINICAL EVALUATION PLAN	Planning on how the evaluation in the clinical field will be done	[71]
CLINICAL EVALUATION REPORT	Performance test at the hand of a literature study and test in the development phase	[71]
CLINICAL EVALUATION REPORT WITH TECHNICAL PERFORMANCE	Validation on the accuracy of the algorithm in the medical field	[71]

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Domain	Deliverable	Ref
CONTINOUS EVALUATION OF CLINICAL USE EXPERIENCE	Controlling of how patients and healthcare providers feel about using the AI system	[89]
CONTINOUS IDENTIFICATION OF UNDESIRED BIAS	Controlling bias which may occur due to training data becoming outdated	[132]
CONTINOUS MONITORING OF POSSIBLE FUTURE DIFFICULTIES	Controlling for mistakes in the AI system or its functionality which can occur in the (near) future	x
CONTINOUS TEST AND EVALUATION CYCLE	Continous controlling and testing of the RELEASED APPLICATION	[14]
CONTRACTUAL ARRANGEMENTS	The different agreements made between the project team, hospital and potential software development company	x
DATA AVAILABILITY	Analysis whether enough information is available for the AI system to run	x
DATA COLLECTION, MODEL AND REPOSITORY	Place where the DATA is stored	[114]
DATA END REPORT	Analysis of the available data, reliability and quality of the produced data, a data dictionary and validation of available data	x
DATA MINIMIZED OR AGREGATED	Non essential data has been removed	[114]
DATA STORAGE	Location where the data is safely kept	x

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Domain	Deliverable	Ref
DATA STORAGE AVAILABLE THROUGH DATA STANDARDS	A check whether the DATA STORAGE upholds previously set standards	x
DEFINITIVE ALGORITHM	A check whether the DATA STORAGE upholds previously set standards	x
DEFINITIVE APPLICATION	Final AI system	x
DEFINITIVE IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
DEFINITIVE PRIVACY STATEMENT	Document for the patients which educates them on how their privacy is kept	[45]
DEFINITIVE PRIVACY STATEMENT AND TERMS & CONDITIONS	Contractual agreement on the participation of the patient in the RELEASED APPLICATION	[45]
DEFINITIVE RISK CLASS	Value assigned to how large the risk is detected in the RISK ANALYSIS for the overall AI system	[142]
DEFINITIVE RISK-BENEFIT ANALYSIS	Analysis with the aim whether the risks weigh up against the positive and negative effects of the AI system	[130]
DEFINITIVE VERSION OF BUSINESS CASE	Outline of the created changes and TANGIBLE VALUE of the RELEASED APPLICATION	[135]
DEMOS OF APPLICATION	Demonstrations given at the hand of the AI system	x
DEMOS OF MVP	Demonstrations given at the hand of the MINIMAL VIABLE PRODUCT	x
DESIRED BIAS ASSESSED	Analysis of the bias within the AI system and how this is kept within limits	[132]

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Domain	Deliverable	Ref
DETERMINED MANUFACTURER	The STAKEHOLDER who will develop the AI system	x
DEVELOPED AI SYSTEM	The working AI system	x
DEVELOPMENT PLAN	Proposed planning of the different development stages of the AI system	[119]
DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
DPIA WHEN CHANGES OCCUR	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
DUE DILIGENCE CHECK	Analysis of the AI system on economic, legal, fiscal and financial aspects	[13]
EFFECTS ON TREATMENT RELATIONSHIP ASSESSMENT	Measurements about the relationship between the healthcare provider and the patients	[19]
END USERS ARE TRAINED	The STAKEHOLDERS which have to use the FINAL APPLICATION have received the correct education	x
ETHICS BY DESIGN	Openly known concepts which guarantee an ethical use of the AI system	[104]
EVALUATION AND LESSONS LEARNED	A look back at the entire process to see what went wrong and what parts could have been improved	x
EXPERT SESSIONS	Session with people with a lot of knowledge in the domain which will validate the processes and the application	[160]
EXPERT SESSIONS WITH AMBASSADORS	Feedback is retrieved at the hand of experts on the subject	[160]

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Domain	Deliverable	Ref
EXPERT SESSIONS WITH USERS	Expert sessions are held with the users of the AI SYSTEM to receive feedback on its use, UI and UX	[160]
FEASIBILITY & CONDITIONS FOR RESPONSIVE USE	A description of the achievability of the project and how to achieve this in an ethical matter	x
FINAL ACCEPTANCE TEST COMPLETED	The last validation of the FINAL APPLICATION	x
FUNCTION CREEP REMOVED	Functionality within the AI system which is no longer wanted or was never in the design and is unwanted	[76]
FUNCTIONAL APPLICATION/FINISHED MVP	A fully working AI system, acting as a minimal viable product for testing	x
FUNCTIONAL MANAGEMENT & SUPPORT AVAILABLE	MANUALS and INFORMATION are available for the end user	x
FUNCTIONAL MANUALS IN PLACE	Written documentation on how to use the AI system	x
FUNDING AGREEMENTS	Contractual agreements on the payments for the development, testing and pilots of the AI system	x
GOVERNANCE AND AGREEMENTS WITH EXTERNAL SUPPLIERS	Contractual agreements with the development party which will create the AI system	x

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Domain	Deliverable	Ref
IDEA DESCRIPTION	At the hand of the SCQ method the solution is described, including any alternatives	[101]
IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have	[151]
IMPACT ON INEQUALITIES	Defenition of positive and negative consequences the final product and its development can have on equalities to prevent bias	[151]
IMPLEMENTATION PLAN	Planning of the different stages in which the FINAL APPLICATION will be implemented in the current environment	[35]
INCENTIVE ANALYSIS	Analysis of performance and effort expectancy, social influence and facilitating conditions	[55]
INFORMATION AND PROMOTION	Educational content and promotional material for the different STAKEHOLDERS on the FINAL APPLICATION	x
INFORMATION SECURITY RISK CLASSIFICATION	Value assigned to how large the risk is detected in the RISK ANALYSIS for the information security	[142]
INFORMATON SECURITY FOR PRODUCTION	Procedures and protection for data	[142]
INFORMED CONSENT FOR DATA USE	Document where a patient agrees with using the AI system	[15]
INVESTIGATIONAL MEDICAL DEVICE DOSSIER (IMDD)	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]

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Domain	Deliverable	Ref
JUSTIFICATION OF UTILITY AND NEED (SOCIAL RETURNS)	Reasoning about why the AI SYSTEM should be used and how society can profit from its use	[10]
KILL SWITCH IN PLACE	A method to immediately stop the AI system if necessary	x
LIABILITY ANALYSIS	Analysis of which legal requirements the AI system has to meet	x
LIMITS OF USE	Rules on for which functionalities the AI system can be used and where its limits are	x
LIST OF STOP CRITERIA	List of occurrences whenever the AI system no longer can be used	[64]
MARKET SCAN	Analysis of how many customers there might be for the project and main competitors	[41]
MEASURING AND MONITORING SYSTEM IN PLACE	Different systems which aid to the different monitoring processes which aid the AI SYSTEM when fully integrated	x
MEDICAL DEVICE ASSESSMENT	The determination of whether the AI system can be seen as a medical device or as a regular AI system	[61]
MONITORING EFFECT ON THE CARE RELATIONSHIP	controlling of the relationship between patients and healthcare providers	[19]
MONITORING FOR CHANGED FUNCTIONALITY	Controlling if any FUNCTION CREEP occurred	x

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Domain	Deliverable	Ref
MONITORING FOR EXPECTED ADDED VALUE	Controlling whether the AI system upholds to the expected value over time	[154]
MONITORING FOR POSITIVE AND NEGATIVE CONSE-QUENCES	A continuous IMPACT ANALYSIS is done for STAKEHOLDERS	x
MONITORING LEVEL OF TRUST	Controlling the trust patients and healthcare providers have in the AI system	[109]
NEW DPIA FOR PRODUCTION	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
NO CHANGE OF FUNC-TIONALITY CHECK	Analysis whether no FUNCTION CREEP has occurred	x
OPERA-TIONAL AND SOCIAL EFFECTS OF USE	Consequences the AI SYSTEM caused by its use on operational and social level	[165]
PERIODIC RE-CALIBRATION OF RISK CLASSIFICA-TION FOR INFORMA-TION SECURITY	Value assigned to how large the risk is detected in the RISK ANALYSIS for the overall AI system	[142]
PERSONAS	A fictional description of the needs and expectations of the earlier defined stakeholders	[54]

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Domain	Deliverable	Ref
PLAN FOR (INTER)NATIONAL SCALE-UP	Planning to increase the scale of the RELEASED APPLICATION	[111]
PLAN FOR TRANSITIONING TO NEW WORK PRACTICE	Planning on the transition for taking the new AI system into place	x
POST-MARKET CLINICAL FOLLOW-UP PLAN	Initiated to document updates happening as the AI system is running in the clinical field. It reports patients safety and performance	[47]
POST-MARKET SURVEILLANCE PLAN	Controlling on how the AI system functions	[95]
POTENTIAL STAKEHOLDER LIST	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
PROCEDURES AND GOVERNANCE FOR SAFE USE	Different rules and processes are in place not to exceed the	[91]
PROCESS EXPLORATION	Analysis of the current workflow	[83]
PRODUCT DOSSIER CONVERTED FROM IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
PROOF OF CONSENT AND AUTONOMY	Signed form by patients who partake in the use of the AI system	x
PROTOTYPE SOLUTION	A mockup or partly working product to display the functionality	x

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Domain	Deliverable	Ref
QUANTITATIVE AND QUALITATIVE COST/BENEFIT ANALYSIS	Measurements of different demographics about the use of the AI SYSTEM in pilot B. Influences the decision-making process	[94]
RE-EVALUTION IN PLACE FOR CIRCUMSTANCES WHERE LIMITS OF USE ARE EXCEEDED	A re-evaluation for when the LIMITS OF USE are exceeded. Evaluates whether it is still viable to use the AI SYSTEM	x
REFINED BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
RELEASED APPLICATION	The FINAL APPLICATION fully used in the healthcare domain	x
RELEVANT STAKEHOLDER CHECK	A check whether still, all STAKEHOLDERS are relevant or extra stakeholders have to be included	[17]
REQUIRED SUPPORT FOR ACCEPTABLE HUMAN INTERACTION	Knowledge and skills needed by the different STAKEHOLDERS who use the AI system	[151]
RESEARCH QUESTION	Full objective of the project on what to study, scope and potential scale-up	[136]
RISK CLASSIFICATION INFORMATION SECURITY	Value assigned to how large the risk is detected in the RISK ANALYSIS for the information security	[142]
RISK MANAGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]

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Domain	Deliverable	Ref
RISK SCAN	An identification of risk areas and issues that might occur with the project	x
RISK-BENEFIT ANALYSIS	Analysis with the aim of whether the risks weigh up against the positive and negative effects of the AI system	[130]
SCALABLE DEVELOPMENT ENVIRONMENT	The place where the DEFINITIVE APPLICATION will run	x
SCALE UP OPTIONS	Analysis to see how and where there are possibilities for the AI system to become larger	[111]
SOCIAL AND SOCIETAL IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have on society	[105]
SOLUTION LIFECYCLE	A description of the phases the solution will go through and its final outcome	[164],[32]
STAKEHOLDER ANALYSIS	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
STAKEHOLDERS HAVE BEEN INVOLVED	A final check whether all stakeholders are part of the STAKEHOLDER ANALYSIS	x
START ARCHITECTURE	Visualization of the software its infrastructure	[18]
STRATEGIC AMBASSADOR	Person who carries the responsibilities for the project and actively supports the project	x
TANGIBLE VALUE AT THE HAND OF END USER	The added value described at the hand of the final user their perspective	[154]

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Domain	Deliverable	Ref
TECHNICAL MANAGEMENT & SUPPORT AVAILABLE	STAKEHOLDERS which aid the healthcare providers or patients in using the FINAL APPLICATION	x
TECHNICAL MANUALS & DOCUMENTATION	Written documentation on the technical details of the AI system	x
TECHNICAL PLAN FOR SCALE-UP	A predetermined plan on how to allow the AI system to function on a larger scale	[111]
TRAINING	A method taught to different STAKEHOLDERS on how to use the DEVELOPED APPLICATION	x
TRAINING AND SCHOOLING	Educational material on how to use the AI system	x
TRAININGS NEEDS	Necessities for educating STAKEHOLDERS	x
UI EVALUATION	Testing whether the user interaction upholds to set standards	[106]
UNFORSEEN CONSEQUENCES CONSIDERED	Analysis of new issues	x
UPDATED CLINICAL EVALUATION REPORT	Validation on the accuracy of the algorithm in the medical field	[71]
UPDATED DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
UPDATED FUNCTIONAL MANUALS	Written documentation on how to use the AI system	x

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Domain	Deliverable	Ref
UPDATED RISK MANAGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]
UPDATED RISK-BENEFIT ANALYSIS	Analysis with the aim of whether the risks weigh up against the positive and negative effects of the AI system	[130]
USER STORIES	Short stories which can act as requirements for the AI system	[52]
UX AND UI MEASURED ANALYSED AND DOCUMENTED	Measurements of the user experience and the user interface and their usability, looks etc.	[106]
UX AND UI REQUIREMENTS	Necessities on how the AI system should look and how a user should be able to interact with the system	[150]
VALIDATION LIST	List of criteria in which the RELEASED APPLICATION has to apply to	[71]
VALIDATION PLAN	Plan on how to measure the ADDED VALUE	[71]
VALORISATION STRATEGY	The strategy which is described at the hand of where the action is taken place, its objectives and areas	[82]
VERIFICATION OF NORMS AND VALUES	Test whether the system test applies to the different ethical values	[148]
WMO CLASSIFICATION	Validation where the AI system is a medical device	[29]

C.10 Dashboard code

This appendix will be used to show the Python code of the dashboard for future use if I get the dashboard to work again

Appendix D

PDD revised version

This appendix shows the second iteration of PDDs created for the methods used by the UMCU.

For a better view, go to: `https://drive.google.com/file/d/1WVaBCAtvUbgw_id8pBCZhAtiPsc_sbgk/view?usp=sharing`

D.1 Changelist

Table D.1: Changelist

Change	**Location**
Fixed typos and other textual errors	All
Add Check for unfinished deliverables activity	PDD phase 1
Add UNFINISHED DELIVERABLES concept	PDD phase 1
Add conditionality to redo missing activities or continue	PDD phase 1
Made PROJECT REPORT 1 a complex concept	PDD phase 1
Removed complex concept from AVAILABLE FUNDS	PDD phase 1
Added PRIORITIES as properties instead of standalone concept to TIMELINE NEXT PHASE	PDD phase 1
Added MDR/IVR CLASS as properties instead of standalone concept to MEDICAL DEVICE DETERMINATION	PDD phase 1

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Change	**Location**
Add Check for unfinished deliverables activity	PDD phase 2
Add UNFINISHED DELIVERABLES concept	PDD phase 2
Add conditionality to redo missing activities or continue	PDD phase 2
Added PRIORITIES as properties instead of standalone concept to TIMELINE NEXT PHASE	PDD phase 2
Add Check for unfinished deliverables activity	PDD phase 3
Add UNFINISHED DELIVERABLES concept	PDD phase 3
Add conditionality to redo missing activities or continue	PDD phase 3
Added PRIORITIES as properties instead of standalone concept to TIMELINE NEXT PHASE	PDD phase 3
Removed DESIGN CRITERIA concept and moved aggregations to DESIGN REQUIREMENTS	PDD phase 3
Added approval as property to CCMO REQUEST	PDD phase 3
Add Check for unfinished deliverables activity	PDD phase 4
Add UNFINISHED DELIVERABLES concept	PDD phase 4
Add conditionality to redo missing activities or continue	PDD phase 4
Added PRIORITIES as properties instead of standalone concept to TIMELINE NEXT PHASE	PDD phase 4
Add Check for unfinished deliverables activity	PDD phase 5
Add UNFINISHED DELIVERABLES concept	PDD phase 5
Add conditionality to redo missing activities or continue	PDD phase 5

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Change	**Location**
Removed complex activity Check available resources and create a timeline on next phase	PDD phase 5
Add Check for unfinished deliverables activity	PDD phase 6
Add UNFINISHED DELIVERABLES concept	PDD phase 6
Add conditionality to redo missing activities or continue	PDD phase 6
Add MISSING DELIVERABLES TO idea phase	Zenya PDD
Add MISSING DELIVERABLES TO exploration phase	Zenya PDD
Add MISSING DELIVERABLES TO development phase	Zenya PDD
Add MISSING DELIVERABLES TO pilot A phase	Zenya PDD
Add MISSING DELIVERABLES TO pilot B phase	Zenya PDD
Add MISSING DELIVERABLES TO the implementation phase	Zenya PDD

D.2 PDD Zenya

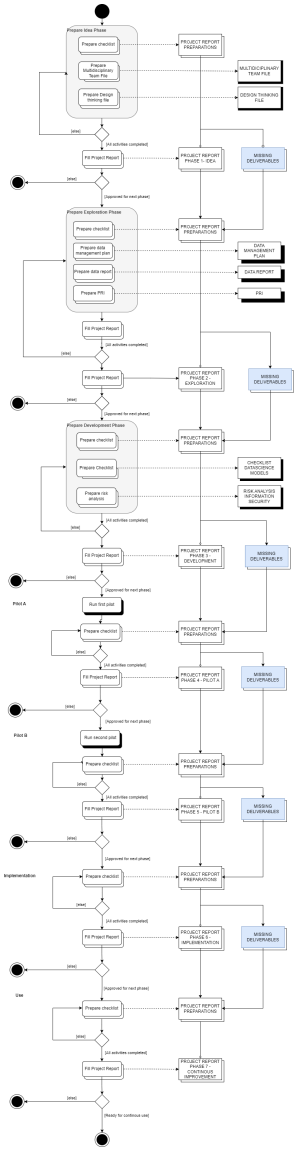

Figure D.1: PDD Zenya platform

D.2.1 Activity Table

Table D.2: Activity table Zenya

Activity	Sub Activity	Description
Prepare Idea Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Prepare multidisciplinary file	
	Prepare design thinking file	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Exploration Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Prepare data management plan	
	prepare data report	
	prepare PRI	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Development Phase	Prepare project report	The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
	Pepare checklist	
	Prepare risk analysis	
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Run first pilot		A pilot is run without real patients or within a safe environment

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Activity	Sub Activity	Description
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Run Second pilot		The previously created and trained algorithm is tested on real patient data
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report
Prepare Checklist		The researcher does research and prepares the different DELIVERABLES to prepare for the different phases
Fill Project Report		At the hand of the PROJECT REPORT PREPARATIONS PHASE 1, Digital Health fills in the report

D.2.2 Concept Table

Table D.3: Concept table Zenya

Concept	Description
DELIVERABLES	Different information which has to be described by the researcher or in combination with Digital Health for the project to succeed
PROJECT REPORT PREPARATIONS PHASE 1	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
MULTIDISCIPLINARY TEAM FILE	A distribution of team members among different responsible provides an overview of the team and Digital Health
DESIGN THINKING FILE	Provides a template with elaborations of multiple concepts part of PROJECT REPORT PHASE 1 to assist the initiative
PROJECT REPORT PHASE 1	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 1 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 2	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
DATA MANAGEMENT PLAN	A description of which data will be collected, how this data will be collected, where it will be stored, and how it is secured.
DATA REPORT	Overview of information, such as a dashboard, about the data retrieved and how it has been processed
PRI	A predictive risk inventory done to identify risks
PROJECT REPORT PHASE 2	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 1 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 3	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department

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Concept	Description
CHECKLIST DATA SCIENCE MODELS	A checklist which can be used to measure the use of the AI system and its features
RISK ANALYSIS INFORMATION SECURITY	An analysis of the potential risks when collecting, saving, and processing data
PROJECT REPORT PHASE 3	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 3 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 4	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 4	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 4 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 5	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 5	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 5 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 6	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department
PROJECT REPORT PHASE 6	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 6 by Digital Health, upon this document is decided whether the project may continue
PROJECT REPORT PREPARATIONS PHASE 7	At the hand of the actions taken, different DELIVERABLES are prepared for assessment by the Digital Health department

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Concept	**Description**
PROJECT REPORT PHASE 7	A combination of different fields and checklists filled in at the hand of the PROJECT REPORT PREPARATIONS PHASE 7 by Digital Health, upon this document, is decided whether the project may continue
MISSING DELIVERABLES	Deliverables which were not finished during the phase

D.3 PDD Project Report 1 v2

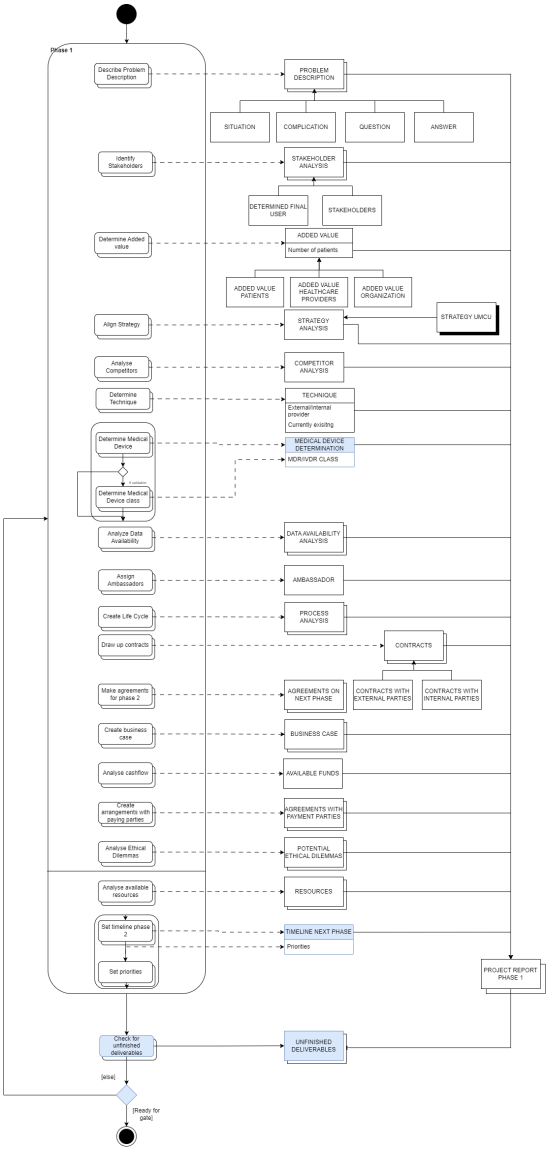

Figure D.2: PDD Phase 1 - Idea v2

D.3.1 Activity Table

Table D.4: Activity table phase 1

Activity	Sub Activity	Description
Prepare Idea Phase	Describe Problem Description	Describe the PROBLEM DESCRIPTION at the hand of the SCQA method
	Identify Stakeholders	Check which FINAL USERS and other STAKEHOLDERS affects the potential product at the hand of a STAKEHOLDER ANALYSIS
	Determine Added value	Measure the amount of ADDED VALUE the proposed solution will have and if this is positive from the perspective of healthcare providers, the organization and patients. Also, determine the number of patients the AI system might affect.
	Align Strategy	Create a strategy for the idea and check whether the idea fits within the strategy at the UMCU, resulting in a STRATEGY ANALYSIS
	Analyse Competitors	Analyse already existing products and algorithms, resulting in a COMPETITOR ANALYSIS
	Determine Technique	Determine the TECHNIQUE needed for the idea to be suitable
	Determine Medical Device	Get an indication whether the device counts as a medical device, saved as a MEDICAL DEVICE DETERMINATION
	Analyze Data Availability	Analyse potential data which can be used at the hand of the DATA AVAILABILITY ANALYSIS
	Determine Medical Device class	Determine what type of MEDICAL DEVICE CLASS the idea would have if the idea its MEDICAL DEVICE DETERMINATION is true
	Assign Ambassadors	
	Create Life Cycle	Draw the potential AI system its lifecycle to do a PROCESS ANALYSIS

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Activity	Sub Activity	Description
	Draw up contracts	Create CONTRACTS with different external AND internal parties
	Make agreements for phase 2	Create AGREEMENT ON NEXT PHASE within the team and management
	Create business case	Create a first sketch of the BUSINESS CASE
	Analyse cashflow	Describe the AVAILABLE FUNDS for the project
	Create arrangements with paying parties	Create AGREEMENTS WITH PAYMENT PARTIES such as insurers which can pay for extra provided care if necessary
		Analyse which POTENTIAL ETHICAL DILEMMAS you might encounter during the process
	Analyse available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create timeline	Create a TIMELINE for PHASE 2
	Set priorities	Determine which PRIORITIES certain activities might have within the next phase
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.4 PDD Project Report 2 v2

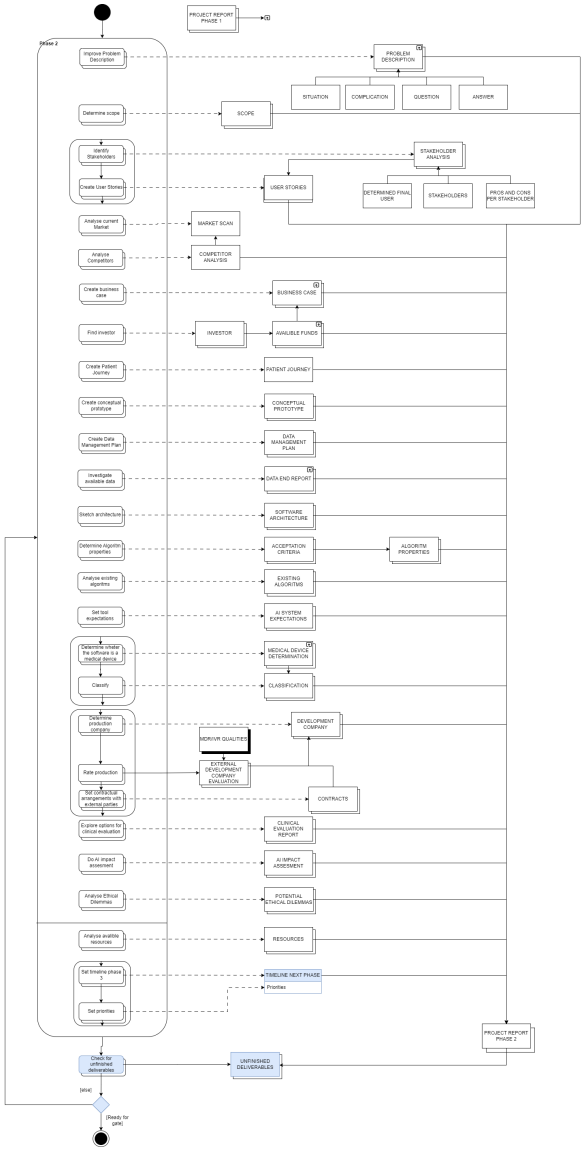

Figure D.3: PDD Phase 2 - Exploration v2

D.4.1 Activity Table

Table D.5: Activity table exploration phase

Activity	Sub Activity	Description
Prepare Exploration Phase	Improve problem description	Improve the PROBLEM DESCRIPTION create in the PROJECT REPORT PHASE 1 at the hand of the SCQA method
	determine scope	Determine the SCOPE the project will act within
	Identify stakeholders	Hold a STAKEHOLDER ANALYSIS, determining people who will influence the project and its users
	create user stories	Create USER STORIES at the hand of the different stakeholders found in the STAKEHOLDER ANALYSIS
	analyse current market	Analyse the current market in a MARKET SCAN
	Create business case	Update the BUSINESS CASE at the hand of the BUSINESS CASE created in PROJECT REPORT PHASE 1
	analyse competitors	Analyse other organizations which have a similar product at the hand of a COMPETITOR ANALYSIS
	find investor	Update whether there is a set INVESTOR and the AVAILABLE FUNDS
	create patient journey	Create a sketch of the PATIENT JOURNEY
	create conceptual prototype	Set up a CONCEPTUAL PROTOTYPE
	create data management plan	Create a DATA MANAGEMENT PLAN
	investigate available data	Set up a DATA END REPORT at the hand of the DATA AVAILABILITY ANALYSIS from PROJECT REPORT PHASE 1
	sketch architecture	Set up a first version of the SYSTEM ARCHITECTURE
	determine algorithm properties	Determine the ALGORITHM PROPERTIES and the ACCEPTATION CRITERIA the final AI system has to adhere to

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Activity	Sub Activity	Description
	analyse existing algorithms	Analyse any EXISTING ALGORITHMS which can be reused for the purpose of the project
	set tool expectations	Create the AI SYSTEM EXPECTATIONS
		Indicate whether the device counts as a medical device, saved as a MEDICAL DEVICE DETERMINATION
	classify software	Determine what type of MEDICAL DEVICE CLASS the idea would have if the idea its MEDICAL DEVICE DETERMINATION is true
	determine production company	Determine the DEVELOPMENT COMPANY
	rate production	If the DEVELOPMENT COMPANY is an external party, determine whether it suffices to the MDR/IVR QUALITIES in an EXTERNAL DEVELOPMENT COMPANY EVALUATION
	set contractual arrangements with external parties	Create CONTRACTS with external DEVELOPMENT COMPANY
	explore options for clinical evaluation	Check how a CLINICAL EVALUATION can take place to test the AI system
	do AI impact assessment	Create an AI IMPACT ASSESSMENT
	Analyse ethical dilemmas	Update the POTENTIAL ETHICAL DILEMMAS which might take place from PROJECT REPORT PHASE 1
	analyse available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create timeline	Create a TIMELINE for PHASE 3
	set priorities	Determine which PRIORITIES certain activities might have within the next phase

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Activity	**Sub Activity**	**Description**
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.5 PDD Project Report 3 v2

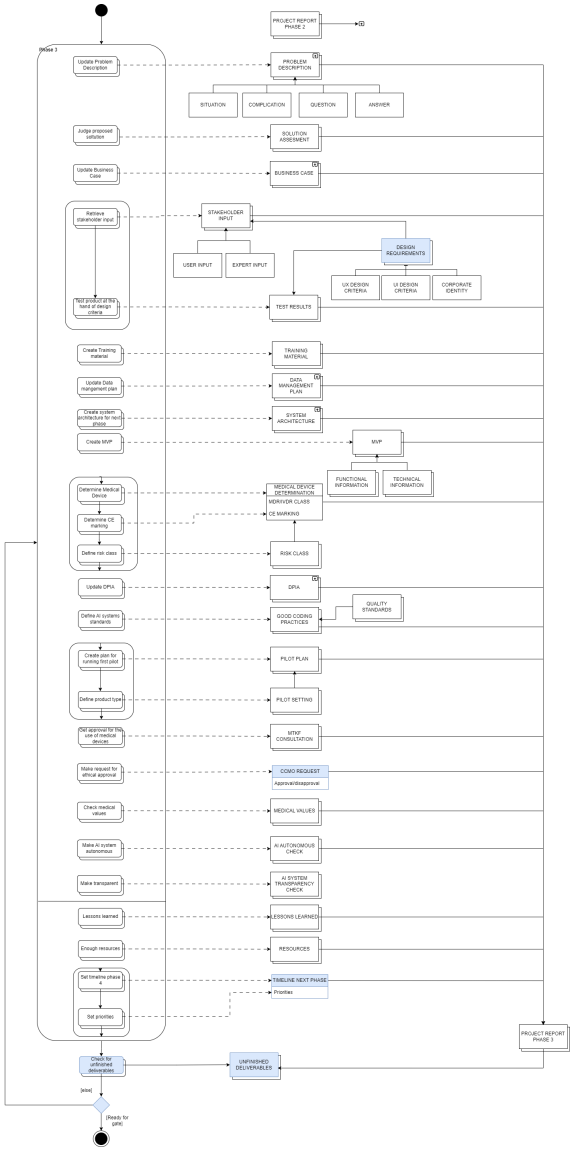

Figure D.4: PDD Phase 3 - Development v2

D.5.1 Activity Table

Table D.6: Activity table development phase

Activity	Sub Activity	Description
Prepare Development Phase	Update problem description	Improve the PROBLEM DESCRIPTION create in the PROJECT REPORT PHASE 2 at the hand of the SCQA method
	judge proposed solution	A SOLUTION ASSESSMENT is done at the hand of presenting the potential solution at the hand of demos
	update business case	Update the BUSINESS CASE at the hand of the BUSINESS CASE created in PROJECT REPORT PHASE 2 and discuss it with the business office
	retrieve stakeholder input	Receive DESIGN REQUIREMENTS at the hand of EXTERNAL STAKEHOLDER INPUT and INTERNAL STAKEHOLDER INPUT
	test product at the hand of design criteria	Test the potential solution at the hand of the set DESIGN REQUIREMENTS
	create training material	Create TRAINING MATERIAL for users
	update data management plan	Update the DATA MANAGEMENT PLAN, created in PROJECT REPORT PHASE 2
	create system architecture	Create the SYSTEM ARCHITECTURE at the hand of the sketched SYSTEM ARCHITECTURE in PROJECT REPORT PHASE 2
	create MVP	Create the MVP
	determine whether medical device	Update the MEDICAL DEVICE DETERMINATION
	define risk class	Set the RISK CLASS for the MEDICAL DEVICE DETERMINATION
	determine if CE marking	Determine whether CE MARKING is necessary for the potential solution
	Update DPIA	Update the DPIA

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Activity	Sub Activity	Description
	define AI systems standards	Define whether the proposed solution applies according to GOOD CODING PRACTICES and its QUALITY STANDARDS
	create plan for pilot	Create a PILOT PLAN
	define product type	Define the PILOT SETTING in which the pilot will take place
	Get approval for check of medical devices	Get an MKTF CONSULTATION to approve the use of the proposed solution
	Make a request for ethical approval	Have the potential solution and the PILOT PLAN checked at the CCMO
	check medical values	Check whether the potential solution applies to the MEDICAL VALUES set
	make AI system autonomous	Check whether the potential solution is autonomous for the end users
	Make AI transparent	Check whether the potential solution is transparent enough and what sensitive data is used at the hand of an AI SYSTEM TRANPARENCY CHECK
	Document lessons learned	Document the LESSONS LEARNED during this phase
	Determine enough resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Set timeline for phase 4	Create a TIMELINE for the next phase
	Set priorities for phase 4	Determine which PRIORITIES certain activities might have within the next phase
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.6 PDD Project Report 4 v2

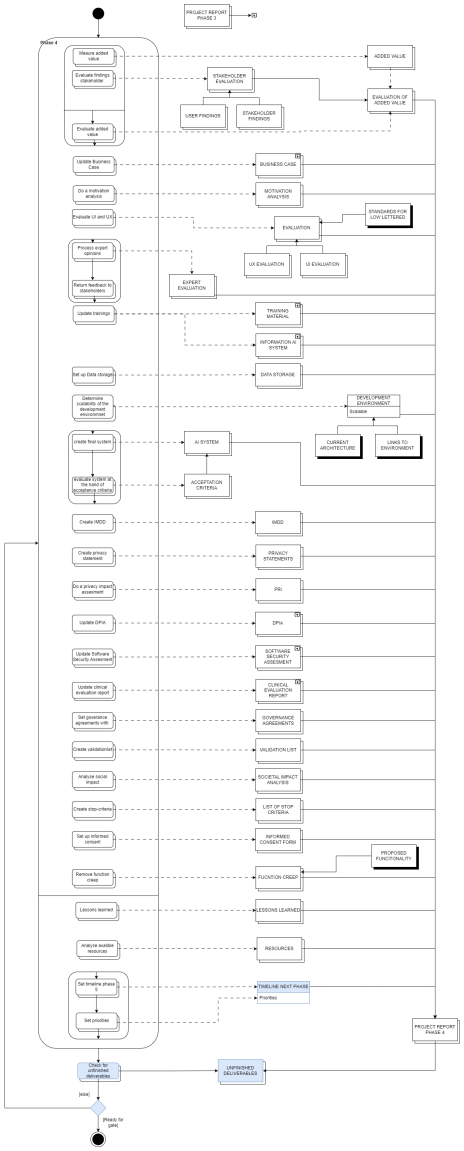

Figure D.5: PDD Phase 4 - Pilot A v2

D.6.1 Activity Table

Table D.7: Activity table pilot A phase

Activity	Sub Activity	Description
Prepare Pilot A Phase	measure added value	Measure the ADDED VALUE during the pilot
	evaluate added value	Evaluate the ADDED VALUE and the STAKEHOLDER EVALUATION
	evaluate findings stakeholder	Evaluate the USER FINDINGS and STAKEHOLDER FINDINGS
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 3
	hold motivation analysis	Create a MOTIVATION ANALYSIS at the hand of the use of the proposed solution in the next phase
	evaluate UI and UX	Evaluate the UI and UX and check if it upholds the STANDARDS FOR LOW LETTERED
	process expert opinions	Hold expert sessions and evaluate their opinions
	return feedback to stakeholders	Return the EXPERT EVALUATION to the stakeholders
	update pieces of training	Update the TRAININGS and INFORMATION for the proposed solution
	Set up data storage	Set up a DATA STORAGE environment for patient data
	measure scalability	Determine whether the DEVELOPMENT ENVIRONMENT is fit for scale-up
	create final system	create the final AI SYSTEM
	evaluate system at the hand of acceptance criteria	Evaluate the AI SYSTEM at the hand ACCEPTATION CRITERIA
	create IMDD	Create the IMDD
	create privacy statement	Create a PRIVACY STATEMENT for clinical use
	do a PRI	Do a PRI

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Activity	Sub Activity	Description
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 3
	update software security assessment	Update the SOFTWARE SECURITY ASSESSMENT created in PROJECT REPORT PHASE 3
	update clinical evaluation report	Update the CLINICAL EVALUATION REPORT created in PROJECT REPORT PHASE 3
	create validation list	Create a VALIDATION LIST with the expected results of the AI SYSTEM
	Analyse social impact	Analyse the SOCIETAL IMPACT of the AI SYSTEM
	create stop criteria	Create a list of STOP CRITERIA
	Set up informed consent	Set up an INFORMED CONSENT FORM for patients
	remove function creep	Remove FUNCTION CREEP at the hand of the PROPOSED FUNCTIONALITY
	lessons learned	Document the LESSONS LEARNED during this phase
	check if necessary resources are available	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	create timeline for phase 5	Create a TIMELINE for the next phase
	Set priorities for phase 5	Determine which PRIORITIES certain activities might have within the next phase
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.7 PDD Project Report 5 v2

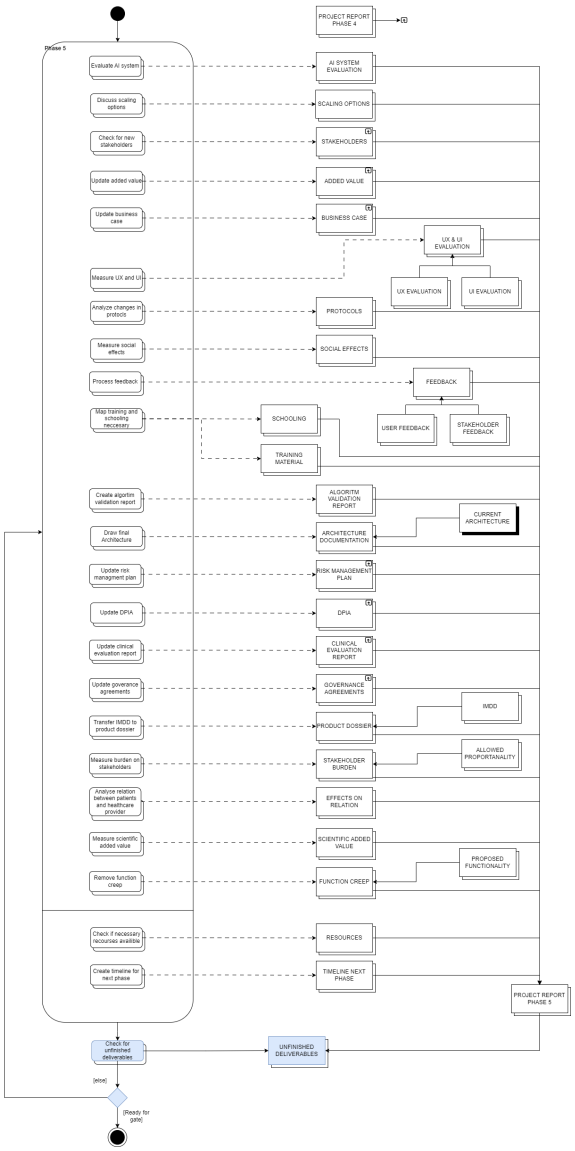

Figure D.6: PDD Phase 5 - Pilot B v2

D.7.1 Activity Table

Table D.8: Activity table pilot B phase

Activity	Sub Activity	Description
Prepare Pilot B Phase	evaluate AI system	Evaluate the AI SYSTEM
	Discuss scaling options	Do a check of the SCALING OPTIONS of the AI SYSTEM
	check for new stakeholders	Check whether the STAKEHOLDERS are still relevant or if new STAKEHOLDERS have come into the picture
	update added value	Update the ADDED VALUE set in PROJECT REPORT PHASE 4 with the measurement from current phase
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 4
	measure UI and UX	Evaluate the UX and UI
	analyze changes in protocols	Check whether the current PROTOCOLS have changed with the use of the AI SYSTEM
	measure social effects	Measure SOCIAL EFFECTS at the hand of the PATIENT JOURNEY created in previous phases
	process feedback	Process the USER FEEDBACK and STAKEHOLDER FEEDBACK
	map training and schooling necessary	Map what SCHOOLING and TRAININGS are needed for the use of the AI SYSTEM
	create algorithm validation report	A data scientist creates an ALGORITHM VALIDATION REPORT
	draw final architecture	Create an ALGORITHM DOCUMENTATION at the hand of the CURRENT ARCHITECTURE
	update risk management plan	Update the RISK MANAGEMENT PLAN
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 4

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Activity	Sub Activity	Description
	update clinical evaluation report	Update the CLINICAL EVALUATION REPORT created in PROJECT REPORT PHASE 4
	update governance agreements	Update GOVERNANCE AGREEMENTS
	transfer IMDD to product product dossier	Transfer the IMDD to the PRODUCT DOSSIER
	measure burden on stakeholders	Measure the STAKEHOLDER BURDEN
	Analyse the relation between patients and healthcare providers	Analyse the RELATIONAL EFFECT between patients and healthcare providers during the use of the AI SYSTEM
	measure scientific added value	Measure the SCIENTIFIC ADDED VALUE of the AI SYSTEM
	remove function creep	Remove FUNCTION CREEP at the hand of the PROPOSED FUNCTIONALITY
	check if necessary resources are available	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create a timeline for the next phase	Create a TIMELINE for the next phase
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.8 PDD Project Report 6 v2

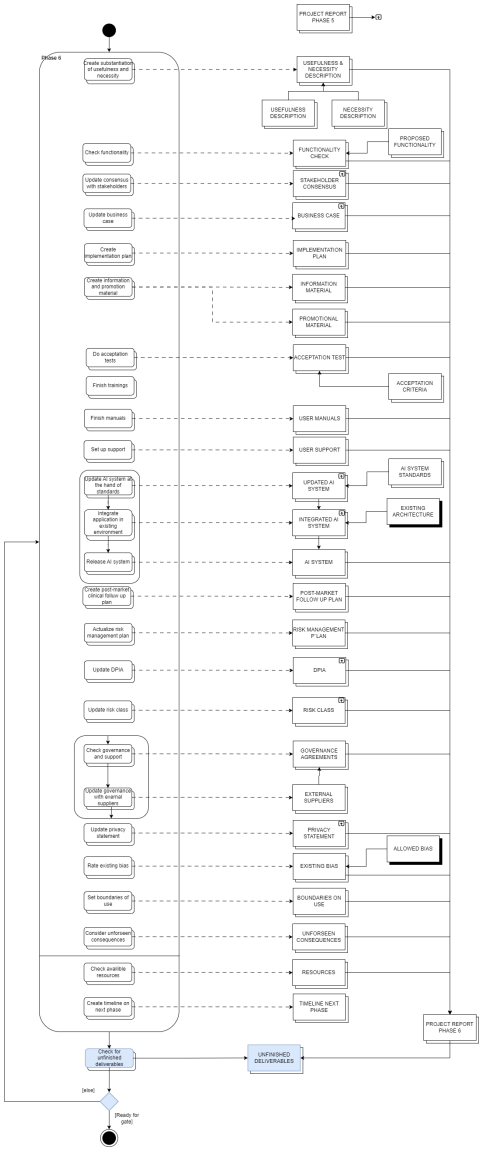

Figure D.7: PDD Phase 6 - Implementation v2

D.8.1 Activity Table

Table D.9: Activity table implementation phase

Activity	Sub Activity	Description
Prepare Implementation Phase	create substantiation of usefulness and necessity	Create a public USEFULNESS DESCRIPTION and a NECESSITY DESCRIPTION
	check functionality	Check whether the functionality of the AI SYSTEM still upholds the PROPOSED FUNCTIONALITY
	update consensus with stakeholders	Update STAKEHOLDER CONSENSUS with
	update business case	Update the BUSINESS CASE created in PROJECT REPORT PHASE 5
	create implementation plan	Create an IMPLEMENTATION PLAN
	create information and promotion material	Create INFORMATION MATERIAL and PROMOTION MATERIAL for the use of the AI SYSTEM
	do acceptation tests	Do ACCEPTATION TESTS at the hand of the ACCEPTATION CRITERIA
	finish trainings	Finish the TRAININGS created in PROJECT REPORT PHASE 5
	finish manuals	Finish the MANUALS created in PROJECT REPORT PHASE 5
	update application at the hand of standards	Update the AI SYSTEM at the hand of the AI SYSTEM STANDARDS
	Set up support	Set up USER SUPPORT for the use of the AI SYSTEM
	integrate application in existing environment	Integrate the AI SYSTEM in the EXISTING ARCHITECTURE
	release AI system	Officially release the AI SYSTEM

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Activity	Sub Activity	Description
	create post/market clinical follow up plan	Create the POST-MARKET FOLLOW UP PLAN
	actualize risk management plan	Update the RISK MANAGEMENT PLAN created in PROJECT REPORT PHASE 5
	update DPIA	Update the DPIA created in PROJECT REPORT PHASE 5
	update risk class	Update the RISK CLASS created in PROJECT REPORT PHASE 5
	Update governance with external suppliers	Update the GOVERNANCE WITH EXTERNAL SUPPLIERS created in PROJECT REPORT PHASE 5
	update privacy statement	Update the PRIVACY STATEMENT created in PROJECT REPORT PHASE 5
	rate existing bias	Rate the EXISTING BIAS at the hand of the ALLOWED BIAS
	set boundaries on use	Set BOUNDARIES ON USE for the use of the AI SYSTEM
	consider unforeseen consequences	Make a consideration of UNFORESEEN CONSEQUENCES
	check available resources	Analyse whether the RESOURCES available are sufficient for the project to run in the next phase
	Create a timeline for the next phase	Create a TIMELINE for the next phase
	Check for unfinished deliverables	Check whether all deliverables are finished, and choose to redo them or do them in the next phase

D.9 PDD Project Report 7 v2

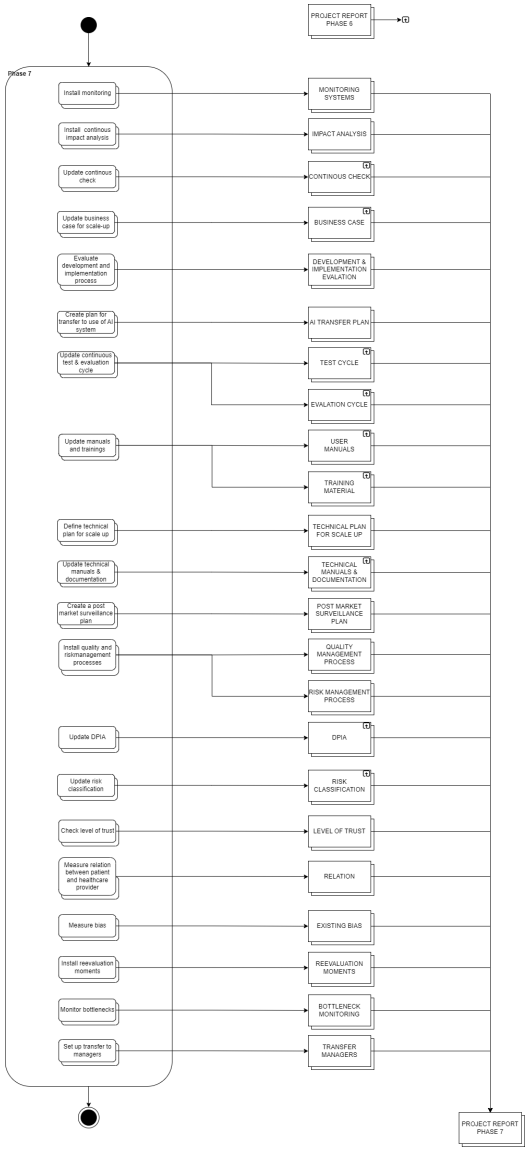

Figure D.8: PDD Phase 7 - Continous Monitoring v2

D.9.1 Activity Table

Table D.10: Activity table use phase

Activity	Sub Activity	Description
	install continuous impact analysis	Install a CONTINOUS IMPACT ANALYSIS
	update continuous check	Create a CONTINOUS CHECK to determine whether the AI SYSTEM functions according to the PROPOSED FUNCTIONALITY
	update business case for scale-up	Update the BUSINESS CASE when scale-up occurs
	evaluate development and implementation process	Create an EVALUATION OF THE IMPLEMENTATION PROCESS with the different stakeholders
	create a plan for transfer to use of the AI system	Create an AI TRANSFER PLAN for the use of the AI SYSTEM
	update continuous test & evaluation cycle	Update the TEST CYCLE and EVALUATION CYCLE
	update manuals and trainings	Update the TRAININGS and MANUALS after implementation
	define technical plan for scale up	Create a TECHNICAL PLAN FOR SCALE-UP
	update technical manuals & documentation	Update the MANUALS and DOCUMENTATION
	create a post-market surveillance plan	Create POST MARKET SURVEILLANCE PLAN
	install quality and risk management processes	Install QUALITY MANAGEMENT PROCESSES and RISK MANAGEMENT PROCESSES
	update DPIA	When changes occur, update the DPIA
	update risk classification	When changes occur, update the RISK CLASSIFICATION

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Activity	Sub Activity	Description
	check level of trust	Measure the LEVEL OF TRUST by users
	measure the relationship between patient and healthcare provider	Measure the LEVEL OF TRUST by users RELATIONSHIP between healthcare providers and patients
	measure bias	Measure the BIAS which occurs at the hand of the AI system and if it complies with the desired bias
	install reevaluation moments	Install different REEVALUATION MOMENT in which measurements take place
	monitor bottlenecks	Monitor the different bottlenecks at the hand of the AI system and its weaknesses
	Set up transfer to managers	Set up TRANSFER MANAGERS which take over the AI system and its responsibilities

D.10 Concept Table v2

Table D.11: Overview of the different Concepts used in the phase PDDs

Domain	Deliverable	Ref
ADDED VALUE	Extra advantages the AI system has at the hand of new functionalities	[154]
ANALYSIS OF PROPORTIONALITY	Determination whether the use of the AI SYSTEM weighs up against its downfalls	[116]
ANALYSIS USEFULNESS IN MEDICAL PRACTICE	Analysis of the usefulness of the final application in the medical field	[40]
APPLICATION ACCEPTED	Application gets accepted by the customer	x
APPLICATION HAS BEEN INTEGRATED INTO ARCHITECTURE	The AI SYSTEM is integrated into the EXISTING ARCHITECTURE	x
APPLICATION MEETS FUNCTIONAL AND OTHER STANDARDS	A check whether the application upholds previous set standards	x
APPLICATION RESPECTS USERS AUTONOMY	Validation whether the application does allow for the user to make its own decision and does not get overruled	[60]
ARCHITECTURE MAP	Visualization of the software its infrastructure	[18]
AVAILABLE FINANCIAL RESOURCES	Amount of money available for the development and implementation of the AI system	x
BEGELEIDINGSETHIEK	Method to aid in applying technology in practice in an ethically responsible manner	[96]
BROADER SCIENTIFIC APPLICATION	Extension study to check whether the AI FINAL APPLICATION is able to be used for other problems	x

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Domain	Deliverable	Ref
BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
BUSINESS CASE OUTLINE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
BUSINESS CASE PART OF HTA	Outline of the proposed changes and TANGIBLE VALUE for the health technology assessment	[25]
BUSINESS CASE SCALE-UP	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
CERTIFICATION PLAN	A planning on how to meet the requirements for the different certifications needed for the AI system	[11]
CHANGES OF PROTOCOL DETERMINED	Determination whether current processes have to be changed	x
CLEAR RESPONSIBILITIES FOR CORRECT USE	A set of rules which limit the use of the AI system to ensure it is not used for non-intended purposes	x
CLIENT/PATIENT JOURNEY	The steps which the patient or healthcare provider will take or undergo whenever using the AI system	[39]
CLINICAL EVALUATION PLAN	Planning on how the evaluation in the clinical field will be done	[71]
CLINICAL EVALUATION REPORT	Performance test at the hand of a literature study and test in the development phase	[71]
CLINICAL EVALUATION REPORT WITH TECHNICAL PERFORMANCE	Validation on the accuracy of the algorithm in the medical field	[71]

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Domain	Deliverable	Ref
CONTINOUS EVALUATION OF CLINICAL USE EXPERIENCE	Controlling of how patients and healthcare providers feel about using the AI system	[89]
CONTINOUS IDENTIFICATION OF UNDESIRED BIAS	Controlling bias which may occur due to training data becoming outdated	[132]
CONTINOUS MONITORING OF POSSIBLE FUTURE DIFFICULTIES	Controlling for mistakes in the AI system or its functionality which can occur in the (near) future	x
CONTINOUS TEST AND EVALUATION CYCLE	Continous controlling and testing of the RELEASED APPLICATION	[14]
CONTRACTUAL ARRANGEMENTS	The different agreements made between the project team, hospital and potential software development company	x
DATA AVAILABILITY	Analysis whether enough information is available for the AI system to run	x
DATA COLLECTION, MODEL AND REPOSITORY	Place where the DATA is stored	[114]
DATA END REPORT	Analysis of the available data, reliability and quality of the produced data, a data dictionary and validation of available data	x
DATA MINIMIZED OR AGREGATED	Non essential data has been removed	[114]
DATA STORAGE	Location where the data is safely kept	x

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Domain	Deliverable	Ref
DATA STORAGE AVAILABLE THROUGH DATA STANDARDS	A check whether the DATA STORAGE uphold previously set standards	x
DEFINITIVE ALGORITHM	A check whether the DATA STORAGE upholds previously set standards	x
DEFINITIVE APPLICATION	Final AI system	x
DEFINITIVE IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
DEFINITIVE PRIVACY STATEMENT	Document for the patients which educates them on how their privacy is kept	[45]
DEFINITIVE PRIVACY STATEMENT AND TERMS & CONDITIONS	Contractual agreement on the participation of the patient in the RELEASED APPLICATION	[45]
DEFINITIVE RISK CLASS	Value assigned to how large the risk is detected in the RISK ANALYSIS for the overall AI system	[142]
DEFINITIVE RISK-BENEFIT ANALYSIS	Analysis with the aim whether the risks weigh up against the positive and negative effects of the AI system	[130]
DEFINITIVE VERSION OF BUSINESS CASE	Outline of the created changes and TANGIBLE VALUE of the RELEASED APPLICATION	[135]
DEMOS OF APPLICATION	Demonstrations given at the hand of the AI system	x
DEMOS OF MVP	Demonstrations given at the hand of the MINIMAL VIABLE PRODUCT	x
DESIRED BIAS ASSESSED	Analysis of the bias within the AI system and how this is kept within limits	[132]

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Domain	Deliverable	Ref
DETERMINED MANUFACTURER	The STAKEHOLDER who will develop the AI system	x
DEVELOPED AI SYSTEM	The working AI system	x
DEVELOPMENT PLAN	Proposed planning of the different development stages of the AI system	[119]
DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
DPIA WHEN CHANGES OCCUR	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
DUE DILIGENCE CHECK	Analysis of the AI system on economic, legal, fiscal and financial aspects	[13]
EFFECTS ON TREATMENT RELATIONSHIP ASSESSMENT	Measurements about the relationship between the healthcare provider and the patients	[19]
END USERS ARE TRAINED	The STAKEHOLDERS which have to use the FINAL APPLICATION have received the correct education	x
ETHICS BY DESIGN	Openly known concepts which guarantee an ethical use of the AI system	[104]
EVALUATION AND LESSONS LEARNED	A look back at the entire process to see what went wrong and what parts could have been improved	x
EXPERT SESSIONS	Session with people with a lot of knowledge in the domain which will validate the processes and the application	[160]
EXPERT SESSIONS WITH AMBASSADORS	Feedback is retrieved at the hand of experts on the subject	[160]

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Domain	Deliverable	Ref
EXPERT SESSIONS WITH USERS	Expert sessions are held with the users of the AI SYSTEM to receive feedback on its use, UI and UX	[160]
FEASIBILITY & CONDITIONS FOR RESPONSIVE USE	A description of the achievability of the project and how to achieve this in an ethical matter	x
FINAL ACCEPTANCE TEST COMPLETED	The last validation of the FINAL APPLICATION	x
FUNCTION CREEP REMOVED	Functionality within the AI system which is no longer wanted or was never in the design and is unwanted	[76]
FUNCTIONAL APPLICATION/FINISHED MVP	A fully working AI system, acting as a minimal viable product for testing	x
FUNCTIONAL MANAGEMENT & SUPPORT AVAILABLE	MANUALS and INFORMATION are available for the end user	x
FUNCTIONAL MANUALS IN PLACE	Written documentation on how to use the AI system	x
FUNDING AGREEMENTS	Contractual agreements on the payments for the development, testing and pilots of the AI system	x
GOVERNANCE AND AGREEMENTS WITH EXTERNAL SUPPLIERS	Contractual agreements with the development party which will create the AI system	x

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Domain	Deliverable	Ref
IDEA DESCRIPTION	At the hand of the SCQ method the solution is described, including any alternatives	[101]
IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have	[151]
IMPACT ON INEQUALITIES	Defenition of positive and negative consequences the final product and its development can have on equalities to prevent bias	[151]
IMPLEMENTATION PLAN	Planning of the different stages in which the FINAL APPLICATION will be implemented in the current environment	[35]
INCENTIVE ANALYSIS	Analysis of performance and effort expectancy, social influence and facilitating conditions	[55]
INFORMATION AND PROMOTION	Educational content and promotional material for the different STAKEHOLDERS on the FINAL APPLICATION	x
INFORMATION SECURITY RISK CLASSIFICATION	Value assigned to how large the risk in detected in the RISK ANALYSIS for the information security	[142]
INFORMATON SECURITY FOR PRODUCTION	Procedures and protection for data	[142]
INFORMED CONSENT FOR DATA USE	Document where a patient agrees with using the AI system	[15]
INVESTIGATIONAL MEDICAL DEVICE DOSSIER (IMDD)	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]

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Domain	Deliverable	Ref
JUSTIFICATION OF UTILITY AND NEED (SOCIAL RETURNS)	Reasoning about why the AI SYSTEM should be used and how society can profit from its use	[10]
KILL SWITCH IN PLACE	A method to immediately stop the AI system if necessary	x
LIABILITY ANALYSIS	Analysis of which legal requirements the AI system has to meet	x
LIMITS OF USE	Rules on for which functionalities the AI system can be used and where its limits are	x
LIST OF STOP CRITERIA	List of occurrences whenever the AI system no longer can be used	[64]
MARKET SCAN	Analysis of how many customers there might be for the project and main competitors	[41]
MEASURING AND MONITORING SYSTEM IN PLACE	Different systems which aid to the different monitoring processes which aid the AI SYSTEM when fully integrated	x
MEDICAL DEVICE ASSESSMENT	The determination of whether the AI system can be seen as a medical device or as a regular AI system	[61]
MONITORING EFFECT ON THE CARE RELATIONSHIP	controlling of the relationship between patients and healthcare providers	[19]
MONITORING FOR CHANGED FUNCTIONALITY	Controlling if any FUNCTION CREEP occurred	x

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Domain	Deliverable	Ref
MONITORING FOR EXPECTED ADDED VALUE	Controlling whether the AI system upholds to the expected value over time	[154]
MONITORING FOR POSITIVE AND NEGATIVE CONSE-QUENCES	A continuous IMPACT ANALYSIS is done for STAKEHOLDERS	x
MONITORING LEVEL OF TRUST	Controlling the trust patients and healthcare providers have in the AI system	[109]
NEW DPIA FOR PRODUCTION	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
NO CHANGE OF FUNC-TIONALITY CHECK	Analysis whether no FUNCTION CREEP has occurred	x
OPERA-TIONAL AND SOCIAL EFFECTS OF USE	Consequences the AI SYSTEM caused by its use on operational and social level	[165]
PERIODIC RE-CALIBRATION OF RISK CLASSIFICA-TION FOR INFORMA-TION SECURITY	Value assigned to how large the risk is detected in the RISK ANALYSIS for the overall AI system	[142]
PERSONAS	A fictional description of the needs and expectations of the earlier defined stakeholders	[54]

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Domain	Deliverable	Ref
PLAN FOR (INTER)NATIONAL SCALE-UP	Planning to increase the scale of the RELEASED APPLICATION	[111]
PLAN FOR TRANSITIONING TO NEW WORK PRACTICE	Planning on the transition for taking the new AI system into place	x
POST-MARKET CLINICAL FOLLOW-UP PLAN	Initiated to document updates happening as the AI system is running in the clinical field. It reports patients safety and performance	[47]
POST-MARKET SURVEILLANCE PLAN	Controlling on how the AI system functions	[95]
POTENTIAL STAKEHOLDER LIST	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
PROCEDURES AND GOVERNANCE FOR SAFE USE	Different rules and processes are in place not to exceed the	[91]
PROCESS EXPLORATION	Analysis of the current workflow	[83]
PRODUCT DOSSIER CONVERTED FROM IMDD	Dossier created to supply information about the AI system at the hand of laws and regulations for medical devices	[92]
PROOF OF CONSENT AND AUTONOMY	Signed form by patients who partake in the use of the AI system	x
PROTOTYPE SOLUTION	A mockup or partly working product to display the functionality	x

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Domain	Deliverable	Ref
QUANTITATIVE AND QUALITATIVE COST/BENEFIT ANALYSIS	Measurements of different demographics about the use of the AI SYSTEM in pilot B. Influences the decision-making process	[94]
RE-EVALUTION IN PLACE FOR CIRCUMSTANCES WHERE LIMITS OF USE ARE EXCEEDED	A re-evaluation for when the LIMITS OF USE are exceeded. Evaluates whether it is still viable to use the AI SYSTEM	x
REFINED BUSINESS CASE	Outline of the proposed changes and TANGIBLE VALUE for the proposed solution	[135]
RELEASED APPLICATION	The FINAL APPLICATION fully used in the healthcare domain	x
RELEVANT STAKEHOLDER CHECK	A check whether still, all STAKEHOLDERS are relevant or extra stakeholders have to be included	[17]
REQUIRED SUPPORT FOR ACCEPTABLE HUMAN INTERACTION	Knowledge and skills needed by the different STAKEHOLDERS who use the Ai system	[151]
RESEARCH QUESTION	Full objective of the project on what to study, scope and potential scale-up	[136]
RISK CLASSIFICATION INFORMATION SECURITY	Value assigned to how large the risk is detected in the RISK ANALYSIS for the information security	[142]
RISK MANAGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]

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Domain	Deliverable	Ref
RISK SCAN	An identification of risk areas and issues that might occur with the project	x
RISK-BENEFIT ANALYSIS	Analysis with the aim of whether the risks weigh up against the positive and negative effects of the AI system	[130]
SCALABLE DEVELOPMENT ENVIRONMENT	The place where the DEFINITIVE APPLICATION will run	x
SCALE UP OPTIONS	Analysis to see how and where there are possibilities for the AI system to become larger	[111]
SOCIAL AND SOCIETAL IMPACT ANALYSIS	Defenition of positive and negative consequences the final product and its development can have on society	[105]
SOLUTION LIFECYCLE	A description of the phases the solution will go through and its final outcome	[164],[32]
STAKEHOLDER ANALYSIS	People or organizations on which affect the final product or the process, or the process or final product will have an effect on	[17]
STAKEHOLDERS HAVE BEEN INVOLVED	A final check whether all stakeholders are part of the STAKEHOLDER ANALYSIS	x
START ARCHITECTURE	Visualization of the software its infrastructure	[18]
STRATEGIC AMBASSADOR	Person who carries the responsibilities for the project and actively supports the project	x
TANGIBLE VALUE AT THE HAND OF END USER	The added value described at the hand of the final user their perspective	[154]

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Domain	Deliverable	Ref
TECHNICAL MANAGEMENT & SUPPORT AVAILABLE	STAKEHOLDERS which aid the healthcare providers or patients in using the FINAL APPLICATION	x
TECHNICAL MANUALS & DOCUMENTATION	Written documentation on the technical details of the AI system	x
TECHNICAL PLAN FOR SCALE-UP	A predetermined plan on how to allow the AI system to function on a larger scale	[111]
TRAINING	A method taught to different STAKEHOLDERS on how to use the DEVELOPED APPLICATION	x
TRAINING AND SCHOOLING	Educational material on how to use the AI system	x
TRAININGS NEEDS	Necessities for educating STAKEHOLDERS	x
UI EVALUATION	Testing whether the user interaction upholds to set standards	[106]
UNFINISHED DELIVERABLES	Deliverables which were not finished during the phase	
UNFORSEEN CONSEQUENCES CONSIDERED	Analysis of new issues	x
UPDATED CLINICAL EVALUATION REPORT	Validation on the accuracy of the algorithm in the medical field	[71]
UPDATED DPIA	The Data Protection Impact Assessment is an analysis method to map privacy risks and personal data processing	[5]
UPDATED FUNCTIONAL MANUALS	Written documentation on how to use the AI system	x

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Domain	Deliverable	Ref
UPDATED RISK MANAGEMENT PLAN	Plan to mitigate the risks which came up in the RISK SCAN	[122]
UPDATED RISK-BENEFIT ANALYSIS	Analysis with the aim whether the risks weigh up against the positive and negative effects of the AI system	[130]
USER STORIES	Short stories which can act as requirements for the AI system	[52]
UX AND UI MEASURED ANALYSED AND DOCUMENTED	Measurements of the user experience and the user interface and their usability, looks etc.	[106]
UX AND UI REQUIREMENTS	Necessities on how the AI system should look and how a user should be able to interact with the system	[150]
VALIDATION LIST	List of criteria in which the RELEASED APPLICATION has to apply to	[71]
VALIDATION PLAN	Plan on how to measure the ADDED VALUE	[71]
VALORISATION STRATEGY	The strategy which is described at the hand of where the action is taken place, its objectives and areas	[82]
VERIFICATION OF NORMS AND VALUES	Test whether the system test applies to the different ethical values	[148]
WMO CLASSIFICATION	Validation where the AI system is a medical device	[29]